



Edited by

Hanna Tolonen • Päivikki Koponen • Arpo Aromaa • Susanna Conti
Sidsel Graff-Iversen • Liv Grøtvedt • Mark Kanieff • Jennifer Mindell
Sanna Natunen • Paola Primatesta • Monique Verschuren
Lucie Viet • Kari Kuulasmaa for the Feasibility of a European Health
Examination Survey (FEHES) Project

Recommendations for the Health Examination Surveys in Europe

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Helsinki 2008



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Kansanterveyslaitos (KTL)

Mannerheimintie 166

00300 Helsinki

Puh. vaihde (09) 474 41, telefax (09) 4744 8408

Folkhälsoinstitutet

Mannerheimvägen 166

00300 Helsingfors

Tel. växel (09) 474 41, telefax (09) 4744 8408

National Public Health Institute

Mannerheimintie 166

FIN-00300 Helsinki, Finland

Telephone +358 9 474 41, telefax +358 9 4744

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1 INTRODUCTION

Kari Kuulasmaa¹, Hanna Tolonen¹, Arpo Aromaa¹

¹National Public Health Institute (KTL), Helsinki, Finland

One of the objectives of the Community Public Health Programme 2003-2008 of the European Union (EU) was to establish and operate a sustainable health monitoring system [1]. As a part of the implementation of the Programme, the European Health Survey System has been outlined [2]. It includes a European Health Interview Survey (EHIS), coordinated by EUROSTAT, the European statistical agency, and a European Health Examination Survey (EHES), coordinated by DG Sanco, Directorate General for Health and Consumer Protection of the Commission of the EU.

The Project “Feasibility of a European Health Examination Survey” (FEHES) of the Public Health Programme has assessed the feasibility of an EHES, or more generally, the feasibility of conducting standardized national Health Examination Surveys (HES) in the European countries [3]. It was concluded that, in nearly all of these countries, it is feasible to carry out some form of a HES in a nationally representative sample. It was also concluded that the standardization of HESs in European countries should be started without delay because in 17 countries there already exist active plans for a conducting national HES in the next five years, and the opportunity for European standardization could be missed.

The purpose of this report is to provide recommendations concerning the resources that will be needed to carry out standardized national HES in the European countries, and to propose standards for such surveys. In particular, recommendations are made on the following:

- Measurements to be included in a national HES (Chapter 3);
- Models for organizing a national HES (Chapter 4);
- Sampling (Chapter 5);
- Recruitment of participants (Chapter 6)
- Legal and ethical issues (Chapter 7);

- Standardized measurement protocols (Chapter 8);
- Data management, documentation and reporting (Chapter 9); and
- Organizing the international collaboration needed by the system of standardized European HESs (Chapter 11).

The report also provides information geared towards national decision makers on the role of a HES as a source of health information (Chapter 2) and to the organizers of the HESs on preparing a budget for the HES (Chapter 10).

The recommendations are mainly based on a review of the experience gained with earlier HESs and recent methodological developments, which the FEHES Project has prepared and published separately [3]. Before the recommendations were finalized, drafts were reviewed and discussed in a workshop, whose participants included experts from all EU Member States, EFTA/EEA countries, EU candidate countries, national HESs of the USA and Canada, WHO, OECD, relevant projects of the Public Health Programme, and relevant agencies and parts of the EU Commission.

The FEHES Project has published a separate document which makes a recommendation for the European Commission concerning the actions needed to facilitate the establishment of a sustainable HES system in the Member States [4].

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2 WHY HEALTH EXAMINATION SURVEYS?

Arpo Aromaa¹

¹National Public Health Institute, , Helsinki, Finland

2.1 INTRODUCTION

Information on health can be obtained from various sources such as registers and health surveys. Depending on their coverage, registers can provide an overview of health, providing information such as mortality, cause-specific morbidity for certain diseases, and the use of healthcare services and medications. However, the information is limited to the users of health care services. To obtain information on health, diseases, healthcare use and their determinants for the entire population, health surveys are needed. An advantage of surveys compared to registers, is that data on health and the use of healthcare and their socioeconomic determinants can be gathered simultaneously. There are numerous health determinants and indicators of chronic diseases that must be identified by taking physiological, biochemical and clinical measurements, and which can thus only be assessed through HESs.

To have a complete picture of a given population's health, various methods of gathering data must be used. One of the most important methods are HESS, which cannot be replaced by other means and which have been carried out for several decades in North America and in several European countries [1]. A light version of an examination survey has been implemented in the United Kingdom. After the interview, nurses have paid home visits and they have taken blood samples and carried out some measurements. Local and regional risk factor focused surveys have been carried out as part of the WHO MONICA Project [2]. The most comprehensive European HESs are the Finnish studies of 1978-80 [3] and 2000-2001 [4]. In most EU/ EFTA Member States the main source of health survey data are Health Interview Surveys (HISs).

Overall, a comprehensive and well-balanced health information system needs to rely on a combination of registers, interviews and examinations. This chapter deals with specifically with examinations, and in particular, their added value.

2.2 USES OF HEALTH EXAMINATION SURVEYS

National health examination surveys are nationally representative sample studies which gather data of reasonable breadth to describe and analyse health, diseases, functional limitations, health determinants and the need for and use of healthcare services. Many of such data can be collected by HISs but the core information only by examination methods.

The number of topics and measurements included in a HES, as well as the complexity of such surveys, varies. The HES component comprises a varying number of anthropometric, physiological, clinical and performance measurements and tests, and the taking of blood samples. A small-scale version of a HES may merely consists of an interview and a few measurements, whereas the most comprehensive surveys comprise a large number of anthropometric measurements (e.g. height, weight, hip and waist circumference), physiological measurements (e.g. blood pressure, spirometry, bioimpedance, resting ECG), blood samples for serum and DNA, dental examinations, measurements of physical and cognitive functioning, a psychiatric interview and a physician's clinical examination. [1]

Health Examination Surveys have considerable added value over HISs. First, the measurements, tests and diagnostic methods allow for the assessment of parameters that cannot be measured by any other means, such as, blood pressure and biochemical determinations from blood samples. As European populations age, it becomes increasingly important to be able to supplement the HIS questions on functioning with tests and measurements. Second, many of the HES measurements can be standardized better than typical interview questions and instruments. Moreover, the tests and measurements are mostly independent of environmental and cultural differences and changes, and standardization and cultural independence are particularly important for making international and population-group comparisons and for assessing of time trends. In these respect, many of the problems with interpreting differences in interview findings can be avoided or controlled, using both interviews and tests.

2.3 INDICATORS MEASURED BY HEALTH EXAMINATION SURVEYS

Table 2.1 described the current ECHI short list (2007) and specifies the topics to be measured by a HESs. However, with development of the short list and the advancement of examination survey methods, new HES topics will be added to the present short list.

Table 2.1 The ECHI shortlist, divided by two grades of availability of data and by the contribution of HES

Indicator class	Regularly available, reasonably comparable.	Partly available, sizeable comparability problems.
Demographic and socio-economic factors	<ul style="list-style-type: none"> • Population by gender/age • Birth rate • Mother's age distribution (incl. teenage pregnancies) • Fertility rate • Population projections • Population by education • Population by occupation • Total unemployment • Population in poverty 	
Health status	<ul style="list-style-type: none"> • Life expectancies • Infant mortality • Perinatal mortality • SDR Eurostat 65 causes, ages • 0-64, 65+ Drug-related deaths • HIV/AIDS incidence • Lung cancer incidence • Breast cancer incidence • (low) birth weight • Injuries road traffic • Injuries workplace • Perceived general health • Prevalence of chronic illness* • Limitations of usual activities* • Related health expectancies* 	<ul style="list-style-type: none"> • Smoking-related deaths • Alcohol-related deaths • Diabetes prevalence • Dementia/Alzheimer prevalence • Depression prevalence • AMI incidence and prevalence • Stroke incidence • Asthma prevalence • COPD prevalence • Injuries: home/leisure, violence • Suicide attempt • General musculoskeletal pain • Limitations in physical functions • Psychological distress • Related health expectancies
Health determinants	<ul style="list-style-type: none"> • Regular smokers • Total alcohol consumption • Intake of fruit • Intake of vegetables • PM10 exposure 	<ul style="list-style-type: none"> • Body mass index • Blood pressure • Pregnant women smoking • Hazardous alcohol consumption • Use of illicit drugs • Physical activity • Breastfeeding • Social support • Work-related health risks

Indicator class	Regularly available, reasonably comparable.	Partly available, sizeable comparability problems.
Health interventions: health services	<ul style="list-style-type: none"> • Vaccination coverage children • Breast cancer screening • Cervical cancer screening • Hospital beds • Physicians employed • Nurses employed • Technologies (MRI, CT) • Hospital in-patient discharges • Hospital daycases • Daycase-discharge ratio • ALOS • GP utilisation (surveys) • Surgeries (PTCA, hip replacement, cataract) • Insurance coverage • Expenditures on health • Cancer survival rates 	<ul style="list-style-type: none"> • Mobility of professionals • Other outpatient visits (surveys, besides GP) • Equity of access • Medicine use • Waiting times elective surgeries • Surgical wound infections • Cancer treatment quality • Diabetes control • Patient mobility

The following section summarises the data that are typically collected only or applying HESs methods (as a supplement to other means).

1. Personal health determinants and risk factors

Blood pressure: usually casual clinic BP, possibly home BP. Biochemical and immunological measurements from blood samples or other tissue samples: typically, serum cholesterol, LDL cholesterol, HDL cholesterol; blood glucose; HbA1c (for diabetes control), cotinine (for smoking), inflammation markers, antibodies (for certain infections), cytokines, biomarkers (e.g. trace elements, vitamins, polyphenols, other antioxidants reflecting diet).

Other determinations from blood samples: haematology; DNA for genetic studies for delineating high risk groups.

2. Symptoms

Symptom questionnaires (when part of a disease-specific diagnostic set they are usually defined as HES methods): examples include the Rose chest pain questionnaire,

the MRC respiratory symptom questionnaire, the General Health Questionnaire (mental symptoms), and the WHO CIDI diagnostic questionnaire on mental disorders.

3. Findings

Typical examples are high blood pressure, ECG signs of myocardial infarction and reduced peak expiratory flow.

4. Diseases

Assessments carried out by doctors or dentists provide estimates of the prevalence estimates of common chronic diseases and conditions, including cavities and gingivitis.

5. Functioning and functional limitations

Tests such as hand grip strength, step test (climbing two stairs), chair stand, walking speed, memory, reaction time, spirometry (respiratory function).

6. Treatment

The reported use of medications can be accurately determined by both HISs and HESs. However, HESs can be used to measure the concentrations of several medications, so as to ascertain whether the medication has been used and whether its concentration is in the recommended therapeutic range. An example is assessment of diabetes treatment based on HbA1c. Other examples are comparisons of blood pressure and lipid levels to target values, or assessing the proportion treated out of those needing treatment.

7. Occurrence of diseases and disorders

When estimating the occurrence of diseases and disorders HESs can contribute much more than other data sources. In particular HIS information on these conditions is rarely valid. In the following there are some examples requiring a combination of interview with tests or clinical assessments:

- Diabetes

- Metal depression
- Prevalence of chronic illness
- Functional limitation (vision, hearing, physical functioning, cognitive and mental functioning)
- Prevalence of dental caries and gingivitis
- Allergic conditions
- Asthma
- COPD
- Low back disorders
- Neck disorders
- Osteoarthritis (arthrosis) of the lower limbs
- Other musculoskeletal disorders

2.4 ADDED VALUE OF HES

This evaluation of the added value of performing examinations is based on a scenario where much of the needed information is already available from HISs and registers. Given that HISs and HESs overlap or are carried out in combination, it is not always easy to classify methods into one of the two categories. We define HES methods as those including anthropometric and physiological measurements, measurements of functioning, clinical examinations and determinations made on blood and other tissue samples. They typically comprise questionnaire on disease-specific symptoms and extensive psychiatric interviews. Most of these take a relatively long time to carry out, and they require specially trained healthcare personnel, and special equipment.

There are some data that can only be obtained with HES methods. Some classical examples are cardiovascular disease risk factors such as blood pressure and serum lipids.

HESs can add a great deal of information and precision to the data obtained with interviews. Examples include many major public health problems, such as cardiovascular diseases, diabetes, mental disorders and musculoskeletal disorders. Although HIS information is of use, comparisons of HIS and HES have unequivocally

shown that the HES data lead to more accurate information on prevalence and incidence. [1]

Whereas height and weight can be reported with reasonable validity (overestimation of height and underestimation of weight is typical), other anthropometric measurements cannot. When gathering and interpreting data on the population's health and risk factors the need for valid anthropometric data has increased. These data can only be obtained through HESs.

To assess the occurrence of osteopenia and osteoporosis, there is no alternative to HES methods. Although it is not feasible to use the large standard machines (DEXA) in field surveys, approximate measurements by ultrasound or X-ray may prove to be quite useful, and have great prognostic value for the risk of hip fracture. Since replies to interview questions on osteoporosis are completely inadequate, it is important to develop the use of direct measurements.

Similarly, cavities, gingivitis, and other oral health conditions can not be self-reported. Some 20-30 years ago, the number of missing teeth was used as an indicator, yet with improving dental health, this has lost its utility. To have valid data, a dentist's clinical examination, possibly supplemented by X-rays, is needed.

HES methods are essential in other areas as well. A prime example is the description of the population's functioning and functional limitations. Depending on the specific aspect of functioning, the correlation between self-reported data and test results varies from good to poor. There is evidence of relatively weak agreement between clinical measurements and subjective reporting of pain and disability [5], whereas reports on vision and physical functioning are highly correlated with related test results [6, 7]. Since self-reports on functioning (IADL) depend on the differing and changing environment, it is essential to gather data on both personal responses and test results.

Another example is the dietary interview or questionnaire, which provides only approximate information on nutrient intake, whereas blood and tissue samples can be used to estimate the true intakes (or availability) of biomarkers such as vitamins, trace elements, and polyphenols in serum and other tissues.

Finally, self-reported disease and doctors' findings may be at variance. Diagnoses and conditions may be both under-reported and over-reported [8-10]. Many conditions are asymptomatic (e.g. hypertension, chronic infections). If they have been diagnosed by a medical doctor, the interviewee may report that diagnosis; if not, it is unreasonable to expect that an interviewee would be able to report such conditions. Examples of conditions that are difficult to identify with interviews or questionnaires are musculoskeletal diseases, mental disorders, and functional limitations. Moreover,

linguistic, cultural and environmental differences may affect responses, which can undermine the validity and reliability of the results and interfere with their comparison to results from different countries and even regions [11]. Provided that training and quality assurance are high, standard test results are more comparable, and the same is true of standardized diagnostic assessments performed by doctors and dentists.

2.5 CONCLUSIONS

Health examinations add much value to HISs alone, as remonstrated by the HESs carried out in European countries and North America. The type and coverage of the additional information depends on the specific tests and examinations performed. Most of the added value can be obtained by performing comprehensive HESs but also with HESs that focus on data that are not obtainable through HISs or which are insufficiently valid. In fact, HESs are the only way to obtain valid data for many common public health problems, and for numerous other conditions, they can contribute important additional data. HES tests can also be more strictly standardized than HIS data. Furthermore, since HES tests are not affected by cultural and environmental changes to the same extent as HIS data, they are extremely important for comparisons of time trends and cross-sectional comparisons among countries. Well-designed HES combine interviews, questionnaires, tests and examinations and provide much better data on the populations' health than any register or interview survey alone, and both HIS and HES are needed in health monitoring.

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3 CORE MODULE AND ADDITIONAL TOPICS

Paola Primatesta¹, Moushumi Chaudhury¹

¹University College London, London, UK

3.1 INTRODUCTION: CRITERIA FOR TOPIC SELECTION

The criteria used to identify and prioritise the topics to include in a European HES are (in no particular order) as follows:

- Inclusion in previous national HESs;
- Availability of international standards;
- Clear interpretation of the results;
- Practicality/ease of administration;
- Acceptability to the respondent;
- Ethical acceptability; and
- Costs.

The priorities regarding the topics to include in national HESs are based on the objectives and criteria that the Public Health Programme has adopted in developing health indicators. The ECHI project was set up to develop health indicators (see list in Annex 1 of Chapter 2) that could be used to provide comparable information on health in Europe and that had to be:

- Comprehensive;
- Meeting user needs;

- Based on earlier work (e.g. WHO, OECD work in the area of indicators selection and definition);
- Innovative; and
- Based on the results of the Health Monitoring Programme and Public Health Programme.

Inherent to these criteria is the concept that the identification of indicators cannot be considered as a fixed, “once and for all” process. Flexibility is needed so that topics emerging over time can be identified and incorporated into future surveys.

In the Review report [1] that was carried out as part of the FEHES project, it is clear that many countries have prioritised similar topics and have used protocols for measurements that on the surface may seem to be similar. However, to provide useful and internationally comparable information, surveys must use standardised procedures and methods, meeting certain methodological and quality criteria (e.g. validity, sensitivity, and timeliness), which allows for the following:

- the identification of changes in the natural history of the disease;
- the avoidance of biases (e.g. those produced by diagnostic fashions and changes in coding practices or measurement procedures);
- the collection of extensive information on events, allowing for in-depth analyses, such as the monitoring of the use of treatments, diagnostic tools etc.;
- the comparability of data among different populations and different time points; and
- the comparability of data from different surveys.

In accordance with the ECHI list, the following four key areas have been identified for inclusion in a HES that has the objective of collecting internationally comparable information on health:

- demographic and socioeconomic factors;
- health status/disease;
- health determinants/health-related behaviours; and
- health interventions/health systems.

Based on that which is described in the Review Report [1], we can conclude that these four key areas also represent the main elements included in the national HESs. Within the four key areas, in accordance with the ECHI shortlist indicators and the review of the most common elements included in previous national HESs, the following topics should be considered for inclusion:

1. Demographic and socio-economic factors:
 - age, sex, occupation, education.
2. Health status/diseases:
 - perceived general health;
 - limitations in physical functions/usual activities;
 - psychological distress;
 - general musculoskeletal pain; and
 - specific disease/conditions: CVD, diabetes, mental health, respiratory disease (asthma, COPD), occurrence of other chronic illnesses.
3. Health determinants/health-related behaviour:
 - smoking;
 - alcohol consumption;
 - consumption of fruit and vegetables;
 - physical activity; and
 - social support.
4. Health interventions/health systems:
 - use of health services (for specific health conditions and general use); and
 - use of medications (for specific health conditions and general use).

Although information on these topics can be collected by performing a HIS, to objectively assess health status and health determinants a HES is needed, whose unique contribution is constituted by biological measurements. These measurements need to be

supported by the information collected through questionnaires, and could include: blood pressure, height, weight, waist circumference, blood samples (non-fasting and fasting), a saliva sample (cotinine), a urine sample (cotinine, glucose), respiratory function, ECG, walking speed test, vision test, hand grip test, bone density, physical fitness test.

3.2 CORE AND ADDITIONAL MEASUREMENTS AND QUESTIONS

Based on the above criteria, a basic set of questions and examinations (referred to as core topics) that are considered as the first step for an international HES can be proposed. The proposed approach is to include a basic (core) level which we suggest should be measured for all countries, including examinations and questions. This model takes into account the review of existing HESs in EU countries and Member States; therefore the suggested methods already exist in some countries. However, there may be differences among countries and the methods will need to be standardised and harmonised at the European level to ensure the comparability of results.

The Table 3.1 below summarises the elements of a core set of topics, and additional topics that can be added as modules that are relevant to specific subgroups, such as certain age groups, ethnic groups or other subpopulations of regional/local interest. These modules could be included with increasing layers of complexity on the basis of users' needs and the available resources.

Practicalities need to be considered concerning the survey administration, the length of the questionnaire and the measurements, and the periodicity of the survey (these are addressed in details in Chapter 4). All of these considerations will have an impact on the definition of the core and the additional modules for a European HES. A minimum set of questions could be included in a short module, with a long, more detailed module over a longer span of time, for example every 10 years. A health survey cycle could be envisaged, by which each topic of interest is periodically repeated (periodicity may vary according to national/internationally set criteria). Flexibility needs to be built into the process, to allow for new and emerging public health issues to be covered. The model we propose assumes that the individual questionnaire will take about 1 hour on average to complete, and that the measurements will also take about 1 hour. Evidence suggests that longer surveys are less acceptable to respondents (see Review Report [1] for discussion and references).

Table 3.1 Proposed HES and HIS components of a European Health Examination Survey.

Level of recommendation	Measurements	Questionnaire
Core	<ul style="list-style-type: none"> • Height • Weight • Waist circumference • Blood pressure • Blood sample (non-fasting, e.g. for total-, HDL-cholesterol) • Fasting blood sample (e.g. for glucose) 	<ul style="list-style-type: none"> • Age • Sex • Education • [Occupation/Income] • General health/ general health status • CVD • Hypertension • Hyper/dyslipidemia • Diabetes • Smoking
Other additional topics (not listed in order of importance)	<ul style="list-style-type: none"> • Hip circumference • Ankle/brachial index • Physical fitness test • Lung function test • Physical performance/ functional test (e.g. walking speed test, vision test, hearing test, hand grip test) • Cognitive function test • ECG • Urine sample (glucose, cotinine) • Saliva sample (alternative for cotinine) • Bone density • Other items pertaining to research questions at local level 	<ul style="list-style-type: none"> • Physical activity • Drinking • Use of health services (general)/ medication • Social support • Psychological distress • Respiratory disease (e.g. COPD, asthma) • Use of health services (for specific conditions) • Use of medications (for specific conditions) • Use of contraception and HRT • Diet: fruit & vegetable consumption • Mental health • Oral health • Other items pertaining to research questions at local level

*Note: for oral health, nutrition, and mental health, specific EU working groups are operational.

Table 3.2 Theoretical approach of national HESs based on existing research questions.

E.g 1. Risk for cardiovascular disease	E.g. 2. The health of older people
CVD focus:	Elderly focus:
Core measurements plus:	Core measurements plus:
	Bone density
Physical activity	Functional tests
ECG	Physical activity
Eating habits and fruit and vegetable module	Eating habits

The proposed approach constitutes a model designed to obtain a basic level of health information for all countries. As suggested, more sections/modules could be added according to local interests in different countries. The build-up of the national HESs will depend on the research questions or survey focus. Some suggestions are given in the Table 3.2 above.

The recommendations on how to prioritise the measurements to include were derived by rating each measurement (+++, ++, +), according to the criteria previously listed and illustrated in the Table 3.3 below.

Ethical acceptability is also a basic criteria. Ethical issues concerning HESs are dealt with in Chapter 7.

Table 3.3 Ratings for inclusion in a national HES.

	Inclusion in previous national HESs	Practicality	Acceptability	Low cost	Availability of international standards	Clear interpretation of results
Height	+++	+++	+++	+++	+++	+++
Weight	+++	+++	++	+++	+++	+++
Waist circumference	+++	++	++	+++	+++	+++
Blood pressure	+++	++	++	++	+++	+++
Blood sample	++	++	+	*	+++	+++
Physical fitness test	+	++	++	++	+	+
Lung function test	+	++	++	++	+++	++
Physical performance	+	++	++	+++	+	++
Cognitive function test	++	++	++	+++	++	++
Urine sample	+	++	+	*	*	*
Saliva sample	+	++	++	*	*	*
ECG	+	+	++	+	++	++
Bone density	+	+	++	+	++	++

* depends on the analytes included.

3.2.1 CORE MEASUREMENTS

Specific information about the measurements (including measurement protocol) is presented in Chapter 8. The core measurements recommended for inclusion are: anthropometric measurements (height, weight, and waist circumference), blood pressure and a blood sample (non-fasting in all participants and fasting in a subsample of participants). For height and weight, the best method is for the interviewer/nurse to take

the measurement; using self-reported height and weight should be avoided because of problems with reliability.

A non-fasting blood sample is the minimum requirement; this will be used to measure total cholesterol, HDL cholesterol and glucose (non-fasting). The questions to complement the HES assess awareness and treatment of hypercholesterolemia. A fasting blood sample is needed for the measurement of triglycerides, LDL cholesterol and glucose. The rationale for taking these measurements is provided in Chapter 7, with details on the methodology for taking blood both fasting and non-fasting.

3.2.2 CORE QUESTIONNAIRE

The sections in Annex 1 include the recommended questions on demographic and socio-economic factors and health status recommended for inclusion in the core. Where applicable, the EHIS questions should be used for the HIS component of the survey. Some countries may have the possibility to link the survey data with registry data, in which case the information on socio-demographic characteristics may be available through linkage with registry data. However, data linkage is not available in all countries and issues related to confidentiality may limit their use. It is therefore recommended that the sections on household income and occupation be included in the HES.

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4 HEALTH EXAMINATION SURVEY MODELS AND SURVEY ORGANIZATION

Päivikki Koponen¹, Kari Kuulasmaa¹, Hanna Tolonen¹

¹ National Public Health Institute, Helsinki, Finland

4.1 HEALTH EXAMINATION SURVEY MODELS

1. Developing a new national HES
 - European standards should be taken into account in planning and preparation.
2. Incorporating the European HES module(s) into an existing national HES
 - To balance the need to follow national time trends with that of making comparisons among European countries, a specific study may be necessary to compare results of HESs that have been carried out using different protocols.
3. Expanding the existing national HIS with the European HES module(s)
 - A HES always includes a questionnaire, which in some cases may be very extensive (for example, if the HES includes the full EHIS questionnaire, then it also serves the needs of EHIS). There may also be interest in expanding a recently conducted HIS into a HES. In this case, the invitation to participate in the HES should not be limited to HIS participants because this is likely to lower the response rate and thus decrease the representativeness of the HES populations. Instead, all of the persons who had been invited to the HIS, whether they actually participated or not, should also be invited to the HES, so that the HIS questionnaire would

only need to be applied to the HES participants who did not participate in the HIS.

Some countries may wish to conduct pilot studies for collecting information through national health screening services, where a certain age group is invited to undergo screening in a primary healthcare setting. It is necessary to evaluate whether or not these screenings can be standardized to produce data that meet the quality criteria. Key issues in the feasibility of using screenings for national health monitoring purposes are coverage at the population level (avoiding selection bias) and standardization of measurements (e.g. local premises, equipment and training of personnel).

4.2 SURVEY ORGANIZATION

4.2.1 ORGANIZATIONAL RESPONSIBILITIES

The organizational responsibilities of a HES can be divided into as follows (adapted from [1]):

1. Conceptualization and planning: Definition of the objectives and the scope of the survey and planning and preparation of the fieldwork and other survey operation.
2. Operation: Implementation and operation of systems for data collection (fieldwork) and data processing.
3. Quality control: Monitoring of performance, provision of feedback, and ensuring that the results meet pre-established quality standards.

These functions do not necessarily have to be performed by separate agencies: conceptualization, planning and operation can be performed by the same agency, though the quality control should be carried out by an organization without vested interest in the survey and not involved in the operations. A pilot phase is always recommended, and though its objectives and content depend on previous experience and the frequency with which the HES will be conducted, the pilot should be able to do the following (adapted from [2]):

- Reveal critical issues for standardization, such as training needs and key issues for measurement manuals, which is needed to plan the training for the survey personnel and to finalise the survey manuals.

- Test the respondents' willingness to participate and observe their reactions, which is needed to develop different means of motivating the population to participate.
- Record timing and calculate the average duration per participants of the interview(s) and examinations, which is needed to estimate personnel resources and the potential burden for participants.
- Test the use of equipments, computer programmes, data management etc., which is needed to avoid problems in data collection and management, and to obtain better estimates of the required space, equipment, and logistics.
- Familiarise the personnel with potential practical problems, which is needed to avoid unnecessary problems during fieldwork by refining practices when needed.

4.2.2 FIELDWORK

4.2.2.1 SELECTION OF THE SURVEY SITE

The selection of the survey site has to be based on general requirements and local/national practices and cultural factors.

General requirements for the survey site (adapted from [1, 3]):

1. Because it is important to be able to recruit participants easily, the survey examinations should take place near the participants' workplace or residence. Thus the examination centre needs to move often, or several survey teams may be necessary. In national surveys, several examination teams are usually needed, each of which will have to move from one place to another. It is thus advisable to also rotate the survey teams among different regions, which will minimize the effect of survey teams on the regional comparability of the surveys. Local health centres often can provide suitable premises, or specific mobile clinics may be equipped for the surveys.
2. In selecting the survey sites, issues that may affect the measurements and the survey results have to be taken into account, such as access of participants with

limited functional ability, room temperature, sample storage, privacy and the possibility of avoiding unnecessary distractions.

Specific requirements for each measurement have to be taken into account (e.g. the availability of a sound proof environment for audiograms).

The following survey sites may be considered:

1. Home visits may be used as the primary survey site. If other sites are used, it is recommended that home visits be used as an option for persons who are otherwise unable or unwilling to participate (e.g., those with limited physical, mental or cognitive functional capacity).
 - Benefits:
 - easy access for participants;
 - no travel costs for participants;
 - relaxed environment for participant;
 - less "clinic effect" on measurements.
 - Disadvantages:
 - some participants may be unwilling to allow survey personnel into their home;
 - lack of safety of survey personnel who make home visits alone;
 - higher travel costs for survey personnel;
 - time needed for personnel travel;
 - restrictions on the selection of measurement devices and other fieldwork equipment;
 - specific needs for the calibration of equipment;
 - not possible to control the environment or temperature, problems with privacy and distractions if other family members are present.
2. Visits in specific/temporary clinic(s) using survey personnel hired by the survey organizers, with the personnel travelling from one survey site to another.

- Benefits:
 - less personnel travel costs than home visits;
 - less restrictions in selecting measurement devices and other fieldwork equipment than home visits;
 - possible to control the environment.
 - Disadvantages:
 - travel costs and potential problems in access for the participants.
 - requires more activity on the part of the participant, which may lower the response rate.
 - If specific/temporal clinics are used, setting up the clinic
 - If the examination site is set up in a regular healthcare clinic, some of the local equipment may be used and therefore less time may be needed to set up the examination site. However, standardization of the local equipment may be difficult.
3. Clinic visits within the existing healthcare system using the regular healthcare personnel, specifically trained for the survey
- Benefits:
 - less time needed to select personnel and set up the survey site;
 - other benefits, as for temporary clinics.
 - Disadvantages:
 - difficulties in training the personnel to adapt and change regular practices so as follow the survey protocols;
 - in countries where healthcare providers can be chosen freely (i.e. public or private), public attitudes towards the selected healthcare organization may affect participation;
 - Problems with equipment standardization if existing equipments in the healthcare clinics is used.
4. Mobile clinics
- Benefits:

- less travel costs for both participants and personnel;
- standardised environments, which contributes to the standardisation of survey protocols.
- Disadvantages:
 - high cost for setting up and using mobile units.

4.2.2.2 SELECTION OF FIELDWORK STAFF

The selection of fieldwork staff has to be based on general requirements, local/national practices and cultural factors.

General requirements:

1. Legislation regarding the right to practice medicine and nursing in each country has to be taken into account, as do EU directives.
2. Motivation: to ensure the reliability and accuracy of the survey results, specific attention should be given to the personnel's motivation to closely follow the survey protocol.
3. General appearance (clean and neat appearance and good manners), friendliness and interest shown towards participants may affect participation. The age, gender, and ethnicity of the fieldwork personnel need to be taken into account with respect to local/national culture.
4. Willingness and possibility to travel around the country with the survey team, which could be a problem for, for example, persons with small children.

Professional groups that should be considered:

1. Physicians (and dentists) are needed if clinical or diagnostic examinations are carried out and if their presence is required for clinical measurements, which may depend on national regulations.
 - Benefits:
 - may increase participation because of higher professional respect/regard among the population;

- better readiness for acute situations during fieldwork and in interpreting test results and informing participants about their test results (better service to participants may affect willingness to participate).
 - Disadvantages:
 - high cost;
 - greater tendency to stray from the survey protocols and make independent decisions;
 - higher "white coat"/observer effect on some measurements.
2. Nurses: registered nurse generalists with training according to the EU directive [4] are recommended for most measurements.
- Benefits:
 - better adherence to standards in survey protocols;
 - lower cost.
 - Disadvantages:
 - differences among European countries in the degree of professional independence and in the population's respect for this professional figure.
3. Other professional groups: medical-technical assistants, nutritionists, and dental assistants need to be considered for specific measurements.
- Benefits
 - high qualifications for specific measurements
 - Disadvantages
 - restricted roles/tasks

4.2.2.3 QUESTIONNAIRE ADMINISTRATION MODE

Given that the layout of the questionnaires/interview sessions and the timing and mode of data collection may affect the results, these should be standardised for each questionnaire topic. Interviews and questionnaires can be used before, during and after

the health examination. To avoid placing an excessive burden on the participant and selection bias, several phases and modes of administration could be used.

In deciding when to administer the questionnaire following should be considered:

1. When the self-administered questionnaires/interviews are completed before the examination, the responses are not affected by the examination and they can be checked during the examination. However, the time-lag between administering the questionnaire and performing the examination may cause problems with linking the measurement with the questionnaire data. The questionnaires have to be brief and easy to complete, so as not to discourage participation in the examinations. However, the interviewers can be trained to motivate participants to undergo the examination and to schedule a time for the examination that best suits the participant. It is recommended that the questionnaire before examination be restricted to the most important key questions and that it not include questions that may be considered too sensitive.
2. When the self-administered questionnaires/interviews are completed during the examination, the responses can be affected by the examination itself (e.g., the results of hearing measurements on hypertension, knowledge that smoking behaviour can be detected from blood/saliva cotinine, etc.). It is recommended that information on acute symptoms and medication be collected during the examination.
3. Completing the self-administered questionnaires/interviews after the examinations can result in the highest non-response rate. It is recommended that sensitive questions and questions that are less important in light of the survey's main objectives (but which could reveal new topics for research and health policy/healthcare development) be asked after the examination. However, the use of sensitive questions after the examinations should be explained to the participants during the examination to make sure that their final impression of participation in the survey is positive.

Survey questionnaires can be completed either by the respondent or by an interviewer. Both options have advantages and disadvantages (adapted from [1, 3]):

1. Self-administration is cost effective, yet it assumes that respondents are not visually impaired and have a good literacy level. It also requires that all questions be completely self-explanatory. Self-administration eliminates the

interviewer effect but may result in missing data as a result of uncertainty about the question. One way of dealing with the problem of missing data is to have the respondent complete the questionnaire at an examination centre where, if needed, assistance is available and the responses can be reviewed immediately. Self-administration provides more privacy and is particularly suitable for sensitive questions. In self-administration, the questionnaire has to be quite short and easy to follow. It is recommended that self-administered questionnaires be checked and supplemented by survey personnel if needed. Web-based questionnaires can also be considered and may be easier for certain groups in the population. However, they may result in participant selection and should in most European countries be used as an alternative to the traditional paper forms, rather than as an exclusive mode of data collection. The use of web-based questionnaires also requires extra efforts to ensure privacy.

2. Interviews are time consuming and carry additional labour costs, but they eliminate the problems of literacy level and visual impairment and they provide an opportunity to clarify questions. The protocol for such clarifications has to be precisely prescribed to avoid biased responses. Interviews can be conducted either by telephone or face-to-face. Telephone interviews are less expensive but provide no control over the environment in which the interview is conducted. There is a risk that interviewers may introduce a bias by asking leading questions or incorrect prompting. This risk can be reduced, though not fully eliminated, by proper training. If computer assisted interviews are used, the format may be longer without additional burden to participants by using "jump-rules" (screening questions).

4.2.2.4 ORDER OF MEASUREMENTS

General requirements (adapted from [1]) of the order of measurements often has constraints because of logistical requirements, such as subject flow and the duration of the examination. The order should be determined as much as possible by:

1. Importance of the measurement: most important measurements should be made early in the session, in case the participant is unable to complete the full examination (time constraints, limitations in functional capacity, etc.)

2. Sensitivity of the questions: uncontroversial questions should be asked early in the interview to allow participants to become relaxed and comfortable with the procedures.
3. Stressfulness of procedure: it is recommended that blood pressure be measured before venipuncture and other tests/interviews that may be mentally or physically stressful.
4. Order in previous surveys: unless good reasons exist for change, it is suggested that the former order of measurements be maintained.

4.2.2.5 INSTRUCTIONS TO THE PARTICIPANTS

Instructions given to the participants: the invitation letter should include instructions on activities that may affect the survey results, such as eating, fasting, use of medication, physical activity and smoking before the appointment. It is recommended that these activities be recorded on the data collection forms (e.g., time of last meal or cigarette, time of day for the measurements). Instructions on clothing may also be needed (e.g., ease of removal, not restricting movement in measurements of functional capacity). However, cultural norms in clothing should be taken into account. It is also important to provide directions on how to get to the examination site or how the home visit will be conducted, how long the examination will take, and whether or not travel expenses are covered.

4.2.2.6 DURATION OF THE EXAMINATIONS

It is recommended that the participants be informed of the average and maximum length of the examination and that the waiting times at the survey site be kept to a minimum. These aspects should be tested in the pilots. In case of longer appointments and if fasting is required, it is recommended that the comfort/convenience of the participants be taken into account (e.g., by providing a break and offering a free snack after measurements that are sensitive to meals). (Adapted from [1])

4.2.2.7 LOGISTICS

The mobility of the survey teams will need to be taken into account in reserving the equipment for the teams, and the logistics of the survey will need to be planned carefully, including the requirements for transporting the blood samples from the

examination site to the laboratory and the special requirements for data management, so as to avoid loss of data and to facilitate prompt data quality control. One key issue in logistics is providing/mailling feedback to the participants as soon as possible (e.g., on the results of their blood tests). (Adapted from [1])

4.2.3 PERIODICITY AND TIMING OF THE SURVEY

It is recommended that the HES be repeated approximately every five years for the core measurements, and possibly less frequently for the other measurements (e.g., every 10 years). More frequent surveys should be considered if there are specific reasons to do so. There is no general rule for the optimal duration of a survey. A survey lasting a full calendar year has the advantage of adjusting the results for seasonal variation. If the survey lasts more than a few months, particular attention needs to be paid to the temporal coverage of quality control, the re-testing and re-training of the measurers, and the distribution of the dates of examination of all population subgroups (such as defined by age, sex or region) evenly over the whole survey period. A survey with a short duration usually requires a relatively large temporary staff, whereas long or yearly surveys allow for more stable employment of the core staff. (Adapted from [1])

If the survey covers only a part of the year, it is essential to evaluate how the measurement results could be affected by weather and national/regional climate and other issues related to the time of the year (e.g., common cold and flu epidemics). It is recommended that the fieldwork be spread out over several months, and, preferably, exactly the same months should be used in each country/region/survey year.

Time of the week and day: to provide easy access to participants and to minimise the effect of timing on measurement results, both morning, day and evening appointments should be available at least a few days a week and also weekends, if preferred by the participants. However, measurements that require overnight fasting can only be conducted in the morning and may therefore be feasible only for a subsample.

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5 SAMPLING

Johan Heldal¹, Hanna Tolonen², Kari Kuulasmaa²

¹Statistics Norway, Oslo, Norway

²National Public Health Institute, Helsinki, Finland

This chapter provides general recommendations concerning the choices that need to be made when defining the target population for a national HES and drawing a statistical sample. To this regard, some critical issues in carrying out a HES should be pointed out immediately:

- 1) The availability of an adequate sampling frame from which to draw a sample: available frames will differ considerably among the countries that are candidates for carrying out a HES. In particular:
 - a) Coverage. The frame must sufficiently cover the target population.
 - b) Timeliness. The frame must not be too old.
 - c) The frame should contain relevant stratification and contact information.
- 2) The participation rate: a high participation rate is fundamental if the general inferences to be made based on the HES are to be valid.

Point 1 is discussed below; point 2 is addressed in Chapter 6.

The procedures for sampling can be summarised as follows:

- Selection of the sampling frame
- Definition of the Primary Sampling Units (PSUs) (e.g., areas covered by potential examination sites)

- Stratification of the PSUs
- Stratification of the eligible persons by gender and age (if appropriate by the frame)
- Definition of the sample sizes for PSUs and persons
- Sampling of the PSUs
- Sampling of the persons within sampled PSUs.
- Invitation to participate for the sampled persons

5.1 SUMMARY OF RECOMMENDATIONS

5.1.1 TARGET POPULATION

1. The geographical coverage of a national HES should generally be the entire territory of the country.
2. The core target population for a national HES is the set of all persons permanently residing in the country as of a given date of reference date (e.g., January 1st) and who are between the ages of 25 and 64 years in the first year following the reference date.
3. Individual countries can extend the eligible age group, with a lower limit of 18 no upper limit.

5.1.2 SAMPLING FRAMES

1. When available (and when feasible in legal and practical terms), a file with the most recent and best coverage of the individual persons in the target population should be used as the sampling frame. Ideally, this will be a population register. If possible, the main frame can be supplemented with other files to catch parts of the target population not covered by the main frame and for supplementary contact information.
2. If a quality frame with individuals is not available, an updated postal address file can be used.

3. Countries already carrying out national HESs on a sample basis with an established frame may continue to use of the same frame. However, all such frames must be evaluated with respect to the general recommendations and standards proposed for European HESs.
4. Countries not having the frames mentioned in points 1 or 2 below can use a map-frame of the NHANES type.
5. The list of accessible frames listed in the Review Report may not be complete, and not all national health institutes have experience in carrying out surveys. If no acceptable frame seems to be available, the national statistics institute or other national public or private institute that regularly carry out national sample surveys in other fields should be consulted as should the European HES collaborators.

5.1.3 SAMPLING DESIGN

1. The geographical area of a country is divided into PSUs, each of which should be small enough to be served by one examination site and with an acceptable travel distance to the site for all persons living in the PSU.
2. The PSUs are stratified into groups that are as homogenous as possible with respect to available variables that are supposed to be relevant to important health indicators; for this stratification, geography, urban/rural, educational level, mortality figures, etc., may be used.
3. Within each stratum, a sample of PSUs is taken by Proportional to Population Size (PPS) sampling.
4. If feasible by the sampling frame, the population is stratified into demographic strata by gender and 10-year age groups.
5. Within each sampled PSU, an equal probability sample is taken for each demographic stratum by the procedure described above and in Appendix A.
6. If there is interest in focusing on social levels, ethnic groups or groups that are assumed to have a high risk for a given disease, special samples should be taken for these groups independently of the general HES; such groups should not be over-represented within the ordinary HES.

5.1.4 SAMPLE SIZE

1. Assuming a 70% response rate, the total sample size n for a national HES should be at least 4,000 persons. A larger sample size (up to 10-14,000 persons) may be used if more detailed national data are desired. Advanced methods for small area statistics that better exploit the information in the data sets should be applied for such purposes.
2. The number \bar{n} of persons sampled per PSU (site) should be decided by optimality formulae.
3. The number of PSUs sampled should be $m = n / \bar{n}$.
4. The sample (n) should be equally allocated to each of eight gender by 10-year age groups.
5. Within each gender by age group, the sample should be allocated to PSU-strata proportional to the sizes of the groups in the strata.
6. The number m of PSUs to be sampled should be allocated to the PSU-strata approximately in proportion to the total population size of each stratum. If the total budget or the total sample size is increased, the sample should be increased by increasing the number of sampled PSUs (or sites) and not by increasing the sample size within PSUs.

5.2 THE TARGET POPULATION

In a statistical survey, the target population is the set of units for which we want to make statistical inferences. There should be as few exclusions as possible. Ideally, all inhabitants in the country within the given age-groups should be included in the target population.

Given that knowledge on chronic diseases and their risk factors is one of the main reasons for performing a HES, both young and middle-aged adults should be included, if feasible. This is also the most economically active part of the population. For these reasons, the core age group is 25-64 years.

In summary, the target population is characterised by a finite population within a defined area (the country) which is accessible within a defined time frame or at a certain time. The chosen target population has to be described in terms of age and other

demographic characteristics that are important for the sample to be nationally representative.

The target population will sometimes be restricted by practical considerations, including limitations posed by the available sampling frame. Typically, many frames exclude persons living permanently in institutions and illegal residents.

5.3 SAMPLING FRAMES

The availability of sampling frames in European countries, as reported by national experts, is discussed thoroughly in Chapter 7.2.2 of the Review Report [1]. The Table 5.1, lists possible sampling frames in European countries.

Maps are relevant for the first stage of the two-stage design presented in Section 5.3. Some considerations regarding the sample frame are provided below.

Frames that are frequently or continuously updated and that cover the entire target population are preferred. Although population registers usually meet these criteria, in some countries they are not continually updated or do not cover certain population groups (under-coverage); population registers typically only cover legal residents. A population register may also contain individuals who are no longer members of the population (deceased, emigrated), and the information on place of residence may be outdated.

Population registers usually contain information on age and gender, which is useful for defining the core target population and for demographic stratification. They provide the most direct access to the eligible persons with contact information, yet unfortunately they are not available as frames in all countries. Nine European countries with population registers reported that they would use this as the sampling frame if carrying out a HES [1].

A postcode address file, which is used as the sampling frame for the English HES, can be an alternative, if the quality is good. However, with such frames the sampling units are household addresses and the frames do not provide information on the individual persons living in the household. A sampled household has to be contacted to see how many eligible persons it contains, if any. Unlike population registers, such frames may cover illegal residents. If postal addresses are sampled with equal probabilities, an equal probability sample of persons is obtained by inviting all eligible persons in the sampled households to participate in the HES. Such a sample is called a cluster sample. If a HES variable shows positive correlation among members of the same household, this will increase the variance of the estimates made from the sample,

so that a larger sample will be necessary to obtain the same precision. When using a postcode address file, the sample cannot be stratified by age, gender, educational level or other individual characteristics.

Table 5.1 Possible sampling frames

Population register	In a continually updated population register, all inhabitants with valid residence permit are included (however with some time lag).
Census	A census includes the entire population at a fixed time. Problems increase with time since the last update.
Electoral register	Listing adult people eligible for voting in election. Mostly used when population register or an updated census are not available.
General practitioner list or lists from other health care organisations	Lists of patients from physicians (general practitioners, GPs) may cover all citizens in some countries, but in general only those who seek a doctor. The lists may be advantageous for the possibility to include non-citizens or institutionalized, but may be subject to professional secrecy.
Telephone directory	Telephone lists may not include all, and the coverage of households will differ between the countries. The lists often name one family member only, and persons may be listed twice.
Postcode address file	The frame lists each house in the street/area or each private household address, but has not information about the people living at the address. In this way non-citizens are included.
High school/ university lists	The list may be useful for supplementary contact information.
Address list	The list may be useful for supplementary contact information.
Insurance registers	The list may be useful for supplementary contact information.
Maps	Maps of administrative or statistical geographical units along with reasonably good statistics of their population sizes.

Censuses and electoral rolls are in most cases not updated regularly and should only be used as frames if they have been updated quite recently. Electoral rolls may only cover persons registered to vote.

Maps are important for dividing each country into small areas or neighbourhoods that are small enough to be handled by an examination site. Maps may be the basis for carrying out a survey in countries where no individual- or postal code-based frame

exists. This is the case in the US NHANES survey. The design of NHANES is briefly described in [2] as follows: *“In simple terms, NHANES divides the United States into communities. The communities are divided into neighbourhoods. The neighbourhoods are selected at random. From each neighbourhood, housing units are selected at random. Selected households are approached by our interviewers who ask residents a few short questions to determine if their household is eligible for the study”*. The neighbourhoods described here must be small enough to make this approach feasible (see also Chapter 7 of the Review Report [1]).

None of the other frames listed in the table (lists of healthcare providers, telephone directory, address lists, etc.) have the coverage or qualities necessary for use as main frames for a national HES. Whether some of them could be used as supplements to catch groups that are missing in a main frame or for supplementary contact information must be determined for each country.

It is important to identify population subgroups that are not fully covered (or not covered at all) by the sampling frame, as the frame determines for whom the results should be considered valid. Subgroups that are not covered, such as people permanently living in institutions, homeless persons, illegal residents, and temporary residents, should be identified and documented. The target population may have to be redefined according to population groups not covered by the frame, or if a supplementary sampling frame could be used.

Both over-coverage and under-coverage in the frame will cause errors in the estimation of totals and may bias survey statistics. Efforts should be made to remove over-coverage and to detect and document under-coverage. In practice, under-coverage is the main problem.

5.4 SAMPLING DESIGN

In HESs, a number of stationary or mobile examination sites, perhaps as many as 80-100, must be places around the country. Each site will have to cover a limited geographical area. These areas should not be too large, and participants should be able to visit the site without too much inconvenience. If mobile units are used, which may be appropriate in sparsely populated areas, the distances that these sites need to move should be kept within reasonable limits.

Each country must be divided into a set of disjoint potential site-areas. Administrative units can be used if they have an appropriate population size and geographic size. For the site-areas to be small enough, most countries will have to be divided into a much larger number of areas than the number of sites to be established.

This means that it will be necessary to take a sample first of the site-areas and then of the invitees within each sampled site-area. This is called two-stage sampling. In survey methodology, the site-areas are referred to as Primary Sampling Units (PSU) and the invitees as Secondary Sampling Units (SSU).

In most countries, the PSUs must be grouped into disjoint subsets called strata. PSUs belonging to the same stratum should be as similar as possible in terms of the factors that affect the target variables in the survey, yet they do not have to be geographically contiguous. They can vary in population size, though not to a great extent.

In most surveys where the target population consists of individual persons, each person should have the same probability of being drawn to the sample (inclusion probability). However, if we want to have separate estimates for small subpopulations (e.g., a certain geographical area), it may be necessary to over-represent them in the sample. If such populations are not too small and can be readily distinguished within the main sampling frame, this can be done by defining them as separate strata and taking a larger sampling fraction in these strata than in the other strata. However, in many cases (e.g., when considering ethnic groups or subpopulations that are considered to be at some special risk), it would be more appropriate to carry out separate and more targeted surveys based on more specialised frames.

Table 5.2 List of concepts

Primary Sampling Units, PSUs	Geographical areas, examination site areas
Secondary Sampling Unites, SSUs	Invitees in sampled site areas
PSU-strata	Subgroups of PSUs according to geographic or health related factors
Demographic strata	Population subgroups by 10-year age and gender
PPS-sampling	A strategy for giving each PSU a probability of being sampled that is Proportional to its Population Size

The estimates and other analyses based on national HESs will be reported by gender and age. To guarantee that the sample size in all such groups is sufficiently large, the population should be stratified by gender and 10-year age group before sampling (if this is feasible with the given frame) and the groups should have equal sample sizes. These groups will be called demographic strata. Since the population sizes in the demographic strata differ, sampling the same number of persons in each of them

means that the inclusion probabilities will differ among the groups. However, in the design suggested below, equal probabilities will be maintained within each demographic stratum.

The demographic strata intersect the PSUs and their stratification. Combining demographic stratification with a two-stage sampling design and equal probability sample within each demographic stratum has some consequences in terms of the possibility to control the exact sample sizes. However, when non-participation is taken into consideration, in any case completely fixed sample sizes cannot be maintained. Although the text in the box is somewhat technical, it has been provided for those readers who wish to have a more in-depth understanding of the topic.

Consider an arbitrary country. The size of the target population in this country is N and the PSUs in the country are divided into K strata numbered $k = 1, \dots, K$ with populations N_1, N_2, \dots, N_K . Each stratum consists of a number of PSUs, say M_k , in stratum no. k . The PSUs in stratum k are labelled $k1, k2, \dots, kM_k$. In stratum k , we want to take a sample of n_k persons (invitees) by first taking a sample of m_k PSUs and then a sample of invitees within each sampled PSU, so that every potential invitee in the stratum has the same probability of being sampled. At first we ignore the demographic groups when sampling. How should this be done?

First, consider sampling m_k PSUs in stratum k . The population size of PSU j in stratum k is denoted N_{kj} . The recommended strategy is to give each PSU a probability of being sampled that is Proportional to its Population Size. This method of sampling PSUs is called PPS-sampling, that is

$$\pi_{kj}^{(1)} \equiv \text{"Prob. of sampling PSU no. } j \text{ in stratum no. } k" = m_k N_{kj} / N_k.$$

Superscript ⁽¹⁾ indicates that this is a probability at the first stage of the sampling design. We assume that m_k or N_{kj} are not so large that this probability is larger than 1 for any PSU. If this occurs, the largest PSUs must be treated as separate strata and the sample of invitees is drawn in one stage. This can be appropriate in cities with a high population density.

The sample size n_k for stratum k should then be allocated to the sampled PSUs in such a way that every person (e.g. person no. i in PSU j) in stratum k has the same final probability

$$\pi_{kji} = n_k / N_k$$

of being sampled after two stages.

If PSU no. kj has been sampled at the first stage, n_{kj} invitees are sampled from the N_{kj} eligible persons in PSU kj . Each of these persons will then have the probability $\pi_{kji}^{(2)} = n_{kj} / N_{kj}$ of being sampled at stage 2, the same for all individuals 'i' in the PSU. The final inclusion probability for an arbitrary person in stratum k is therefore

$$\pi_{kj}^{(1)} \pi_{kji}^{(2)} = m_k \frac{N_{kj}}{N_k} \frac{n_{kj}}{N_{kj}} = m_k \frac{n_{kj}}{N_k}$$

But this should be equal to $\pi_{kji} (= n_k / N_k)$, implying that $n_{kj} = n_k / m_k$. In other words: When sampling the PSUs with probabilities proportional to sizes, an equal probability sample is obtained in stratum k by allocating the stratum sample size n_k evenly on the m_k sampled PSUs. This is a great advantage, which could not be obtained if the PSUs were sampled with equal probabilities (a frequent mistake). It guarantees that every examination site in the stratum will handle the same number of invitees. For the entire country the same can be obtained approximately if the total number m of sites is allocated to the strata (approximately) by the same proportions as the total sample size n of invitees. [4, 5]

But what happens when we try to allocate the total sample size n (or n_k) with equal numbers to various demographic groups?

First, the proportion of the total population represented by each demographic group will vary both across strata and across PSUs within each stratum. A set of first-stage sampling probabilities $\pi_{kj}^{(1)}$ that is right for the elderly may be wrong for the younger persons and vice versa. If a common set of first-stage probabilities and first-stage sample (of PSUs) is used for all demographic groups, then insisting on equal inclusion probabilities within each demographic stratum across PSUs will produce different sample sizes in different PSUs. This applies for each demographic group, as well as in sum across all demographic groups (Appendix A).

Furthermore, the total sample size for a demographic group in a stratum will depend on which PSUs have been drawn at the first stage. This generates a randomness in the total sample size that makes it impossible to fix the overall sample size for each group completely. However, as shown in Appendix A, the sample sizes will be as desired in expectation. We can set the desired sample size for each demographic stratum in each country and PSU-stratum. But this will only in expectation be the sample size we get. Theoretically, the problem can be resolved with fixed sample sizes if one allows different PSUs to be drawn for different demographic groups. But this will raise the costs and complexity significantly and is not practical. Anyway, non-participation will induce randomness in the size of the final sample of participants.

It should be pointed out that the discussion in the text box related to stage 2 of the sampling design applies only when the sampling frame consists of individuals. If a postal address frame is used, the sampling units will be household addresses and it would not be possible to stratify by demographic group. However, it is possible to give all household addresses in a PSU-stratum the same probabilities of being sampled. If all eligible persons in the sampled households are invited to the survey, this will produce an equal probability sample of persons. However, the number of persons included in this sample will depend on the number of eligible persons in the sampled households, a “take what we get” scenario (i.e., out of control).

However, the discussion concerning stage 1 of the design does apply. To draw a stage-one PPS sample, a frame with individual persons is not necessary; only good estimates of the population sizes in each PSU are needed.

In sampling designs based completely on maps there may be more than two stages. In NHANES there were four. The above theory for two-stage samples can be easily extended [5]

The substitution of non-participants with non-sampled individuals, which is often used in commercial surveys, is not good statistical practice. It does not reduce non-participation bias and may introduce new biases. It is not acceptable in national HES (or HIS).

5.5 SAMPLE SIZE AND ALLOCATION OF SAMPLE

There are sample sizes at two levels to be calculated. First, there is a planned total sample size of invitees, say n . When feasible, this sample size must be allocated to the demographic strata (by 10-year age group and gender) and to the PSU-strata. We recommend allocating equal sample sizes to each demographic stratum in the core part of HES, though larger samples can be used for some strata if a specific country wishes to do so. According to the Review Report, the sample size in recent HES ranges from 3,000 to 12,000 persons. The sample size for each group must then be allocated to the PSU-strata. We recommend that this be done proportional to the population in the demographic group in each PSU-stratum (that is n_{k+j}^*).

Second, the set of m examination sites must be allocated to the PSU-strata. We recommend that this be done proportional to the total (eligible) population size in the strata, although deviations must be allowed for here as well. The proportionality can only be rounded up to an integer number of sites. The number of sites allocated to a

PSU-stratum equals the number of PSUs to be sampled in that stratum at stage 1. To be able to estimate sampling variance, no PSU-stratum should be given fewer than two sites, except when one PSU is a stratum alone.

In the box on page 1, formula (1) shows the structure of the variance of estimates of a population average in a two-stage design and how it depends on the two sample sizes m and n . Formula (3) shows the optimal number of invitees per site given the variance components and the parameters in a cost model (2) that depends on a per-site cost and a per-invitee cost. The formula shows that the larger the variation for a variable within PSUs, compared to across PSUs, the larger the optimal sample size within PSUs and the smaller the optimal number of sites. Furthermore, the cheaper it is to examine an extra person compared to setting up an extra site, the larger the sample size within the PSU should be. The variances $V^{(1)}$ and $V^{(2)}$ are variable-dependent and will give different optimal values for different variables.

Note that the optimal value of \bar{n} does not depend on the total budget or the total sample size, only the variance and cost ratios. This means that if the total budget or the total sample size is increased, the sample should be increased by increasing the number of sampled PSUs (or sites), not by increasing the sample size within PSUs. Reliable figures to put into the formulae will be outlined later.

The variance of an estimate of a sample mean is generally larger in a two-stage design than in a one-stage design. How much larger depends on the variable under study. Good stratification of the PSUs will alleviate this increase at the national level, yet this will not be taken into consideration in the subsequent calculations. If the values of the variable under study are highly correlated within PSUs, meaning that the variance $V^{(2)}$ within PSUs is small compared to the variance $V^{(1)}$ across PSUs, the variance V will tend to be much larger than that of a simple random sample. If V is the variance of an unbiased estimator of a population mean with the two-stage design and V_{srs} is the variance of the equivalent estimator with a simple random sample, the ratio of the two variances is called the design effect, D .

Given the population size N_{kjl} for group l in PSU j in stratum k , the number m_k of PSUs selected in stratum k , and the desired sample size n_{k+l}^* for group l in stratum k , the actual sample size n_{kjl} in that PSU under the premise of equal inclusion probabilities for every person in group l in stratum k is calculated in Appendix A.

Roughly, the sampling variance of an estimate for a population mean in a two-stage design like the one described above can be expressed as

$$V = \frac{V^{(1)}}{m} + \frac{V^{(2)}}{m\bar{n}} \quad (1)$$

where \bar{n} is the average number of invitees per sampled PSU. For a given variable of interest, $V^{(1)}$ can roughly be seen as a measure of the variation of its PSU-means across all PSUs whereas $V^{(2)}$ can be seen as a measure of its average variation within the PSUs. The formula is only completely correct if sampling is done with replacement at both stages, which we do not do in practice. But this will not alter the conclusions below. For a given sample total size $n = m\bar{n}$ or a given budget for the survey, what is the optimal value between m and \bar{n} ?

Assume the total cost C of the survey can be described by the model

$$C = c_0 + c_1 m + c_2 m\bar{n} \quad (2)$$

Here, c_0 is the constant cost which is independent of the size of the sample, c_1 is the cost associated with setting up an examination site in a PSU and c_2 is the costs associated with inviting a person to the survey and examining this person. How is the variance V minimised for a given cost? It can be shown that the optimal value of \bar{n} and m can be given by the formula

$$\bar{n} = \sqrt{\frac{V^{(2)} c_1}{V^{(1)} c_2}} \text{ and } m = n / \bar{n}. \quad (3)$$

Proof of this formula is provided in Appendix B.

Noting that $V^{(1)} + V^{(2)} \approx S^2$, the population variance, we get

$$D = \frac{V}{V_{srs}} \approx \frac{V^{(1)} / m + V^{(2)} / m\bar{n}}{S^2 / n} = \frac{\bar{n} V^{(1)} + V^{(2)}}{S^2} = 1 + (\bar{n} - 1) \frac{V^{(1)}}{S^2}$$

V_{srs} is the variance from a simple random sample. For a prevalence P , $S^2 = P(1 - P)$. For a given total sample size n , the design effect also depends on m and \bar{n} . The smaller m is (and the larger \bar{n} is), the larger the design effect will be. However, doing sample size calculations and not having information that can provide good estimates of D , it is quite common to assume a value of 1.5 for D . $D=1.5$ means that the

total sample size of the two-stage sample will have to be increased by 50% compared to a simple random sample to give the same accuracy. To have full effect, the increase will have to be as an increase in the number of sampled PSUs (m), not an increase in the number of invitees per PSU (\bar{n}).

In MONICA, where most of the samples were taken as one-stage samples, it was required that changes in smoking prevalence between groups from 60% to 40%, 3 mmHg in diastolic blood pressure and 0.3mmol/l in total cholesterol should be detectable with a probability (power) of at least 0.80 (Type II error less than 0.20) at a significance level of 5%. Sample sizes were calculated with design effect of 1.0, like in a simple random sample. For this, a minimum sample size of 200 was required in each gender and 10-year age group. Blood pressure required the largest sample. Assessments based on the results from MONICA suggested a sample size of 200-300 for any subgroup of interest to compare, indicating a minimum sample size of around 2,000 for the entire sample.

Table 5.3 shows the test power, the probability of rejecting a wrong null hypothesis of no difference between demographic strata, for similar alternatives to the null hypothesis as used in MONICA with various sample sizes and design effects. The sample size that corresponds to a power of 0.80 is the required sample size for specific variable and the specific design effect. More precisely, the table shows that total cholesterol requires the largest sample size of the three variables to meet the criteria: at least 352 *responding* invitees in each group (i.e., about 2,800 respondents in all eight age-gender groups) with a design effect of 1.5. Expecting a 70% response rate, at least 4,000 persons should be invited in each national HES. It should be noted that the required sample sizes increase with the square of the standard deviations σ and are thus very sensitive to this parameter.

Table 5.3 Statistical power for pair wise comparisons between groups by group sample sizes and design effects with alternatives used for sample size determination in age-gender groups in MONICA. Sample sizes indicating a power of 0.80 are in bold.

<i>n</i>	Prevalence, $P_1=.60, P_2=.40, \delta =0.20$			Diastolic blood pressure $\delta = 3\text{mmHg}, \sigma = 11^1$			Total cholesterol $\delta = 0.3\text{mmol/l}, \sigma = 1.16^2$		
	Design effects, <i>D</i>			Design effects, <i>D</i>			Design effects, <i>D</i>		
	<i>D</i> =1.0	<i>D</i> =1.5	<i>D</i> =2.0	<i>D</i> =1.0	<i>D</i> =1.5	<i>D</i> =2.0	<i>D</i> =1.0	<i>D</i> =1.5	<i>D</i> =2.0
50	0,516	0,372	0,293	0,276	0,200	0,161	0,253	0,184	0,150
98	0,800	0,628	0,508	0,480	0,344	0,271	0,441	0,315	0,249
100	0,807	0,637	0,516	0,487	0,350	0,276	0,448	0,321	0,253
147	0,929	0,800	0,679	0,647	0,480	0,380	0,602	0,441	0,348
196	0,977	0,899	0,800	0,770	0,597	0,480	0,726	0,552	0,441
200	0,979	0,904	0,807	0,779	0,605	0,487	0,734	0,560	0,448
211	0,984	0,918	0,828	0,800	0,628	0,508	0,757	0,583	0,468
262	0,991	0,943	0,866	0,840	0,675	0,552	0,801	0,629	0,509
317	0,999	0,984	0,944	0,930	0,801	0,680	0,903	0,758	0,634
352	1,000	0,991	0,963	0,951	0,840	0,725	0,929	0,800	0,679
422	1,000	0,997	0,984	0,977	0,899	0,800	0,964	0,866	0,757
469	1,000	0,999	0,991	0,987	0,926	0,840	0,977	0,899	0,800
500	1,000	0,999	0,994	0,991	0,941	0,862	0,983	0,916	0,824
1000	1,000	1,000	1,000	0,991	0,942	0,863	0,984	0,917	0,826
2000	1,000	1,000	1,000	1,000	0,999	0,991	1,000	0,997	0,983

There is no recommended upper limit for the sample size. Increasing the sample will reduce the random error but will not reduce selective participation bias. Larger

¹ The estimate $\sigma = 11$ is based on <http://www.ktl.fi/publications/monica/bp/table8.htm> .

² The estimate $\sigma = 1.16$ is based on http://www.ktl.fi/publications/monica/surveydb/bp/table613_summary.htm

samples may be taken if geographic strata in addition to age groups and gender are desired. However, resources should be spent on recruiting the invited persons rather than on increasing the gross sample in each stratum.

With a design effect D , the variance for an estimated mean value can be calculated as

$$V = D(1 - \frac{n}{N}) \frac{1}{n} S^2$$

where N is the population size. For all countries, the sampling fraction n/N will be very small, meaning that the population size and the “population correction factor” $(1 - n/N)$ has very little impact on the variance and for all practical purposes can be considered equal to 1. Thus, the size of the country has a negligible impact on the sample size required to obtain a given precision, making a survey relatively more expensive for small countries. Table 5.4 shows the Standard Errors ($SE = \sqrt{V}$) obtained for estimates of various prevalences ($S^2 = P(1 - P)$) and sample sizes with a design effect of 1.5.

Table 5.4 Standard Errors for estimated prevalence \hat{P} for various sample sizes with design effect 1.5. ($SE(\hat{P}) = \sqrt{1.5P(1 - P)/n}$)

Sample size, n	Prevalence, P						
	0.01	0.02	0.05	0.10	0.20	0.35	0.50
	0.99	0.98	0.95	0.90	0.80	0.65	
50	0.0414	0.0582	0.0906	0.1247	0.1663	0.1983	0.2079
100	0.0293	0.0412	0.0641	0.0882	0.1176	0.1402	0.1470
200	0.0207	0.0291	0.0453	0.0624	0.0832	0.0992	0.1039
500	0.0131	0.0184	0.0287	0.0394	0.0526	0.0627	0.0657
1000	0.0093	0.0130	0.0203	0.0279	0.0372	0.0443	0.0465
2000	0.0065	0.0092	0.0143	0.0197	0.0263	0.0314	0.0329
5000	0.0041	0.0058	0.0091	0.0125	0.0166	0.0198	0.0208
10000	0.0029	0.0041	0.0064	0.0088	0.0118	0.0140	0.0147

Having estimated a prevalence P with a statistic \hat{P} , a 95% confidence interval can be calculated roughly as $\hat{P} \pm 2SE(\hat{P})$ where $SE(\hat{P}) = \sqrt{1.5\hat{P}(1-\hat{P})/n}$. Sample sizes can be calculated based on required standard deviations by solving for n .

$$n = 1.5S^2 / V$$

If the requirement is formulated by means of the half with d of a 95% confidence interval, which is approximately $2SE$, then this formula can be expressed as

$$n = 1.54S^2 / d^2 .$$

Tor some readers may look more familiar.

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APPENDIX A: TWO STAGE SAMPLE WITH INTERSECTING DEMOGRAPHIC STRATA.

Let $U_k^{(1)}$ be the set of the M_k PSUs in stratum no. k . N_k is its population size and N_{kj} is the population of PSU no. j in that stratum. A sample of m_k PSUs is taken from $U_k^{(1)}$ with inclusion probabilities proportional to their sizes (PPS sampling):

$$\pi_{kj}^{(1)} = m_k N_{kj} / N_k < 1, \quad j = 1, \dots, M_k; \quad k = 1, \dots, K$$

The sample of PSUs will be called s_1 . Let N_{kjl} be the number of persons in demographic group no. l in PSU j in stratum k . $N_{kj} = \sum_{l=1}^L N_{kjl}$. $N_{k+l} = \sum_{j=1}^{M_k} N_{kjl}$ is the number of persons in demographic stratum l in stratum k . We want to take a sample with desired size n_{k+l} from the N_{k+l} in two stages giving every person in the same demographic stratum in the same stratum the same final probability

$$\pi_{kl} = n_{k+l}^* / N_{k+l}$$

of being sampled after two stages. The $*$ indicates that n_{k+l}^* is a “desired” sample size. As seen below, this will usually not be the actual sample size obtained but will be correct “in expectation”. If PSU no. k is sampled, the proportion sampled and also the probability of each person being drawn in PSU k at stage 2 is

$$\pi_{kji}^{(2l)} = n_{kjl} / N_{kjl}.$$

The subscript i indexes the individual persons in the PSU. This probability is the same for every person in the same demographic stratum l . The combined inclusion probability for the first and second stage is

$$\pi_{kji}^l = \pi_{kj}^{(1)} \pi_{kji}^{(2l)} = \frac{m_k N_{kj}}{N_k} \frac{n_{kjl}}{N_{kjl}}$$

But this should equal π_{kl} above yielding the equation

$$\frac{n_{k+l}^*}{N_{k+l}} = \frac{m_k N_{kj}}{N_k} \frac{n_{kjl}}{N_{kjl}}$$

Solving this equation gives

$$n_{jkl} = \frac{n_{k+l}^*}{m_k} \frac{N_k N_{kjl}}{N_{k+l} N_{kj}}$$

Let

$$I_{kj} = \begin{cases} 1 & \text{if PSU no. } kj \text{ is sampled} \\ 0 & \text{otherwise} \end{cases}$$

The probability of I_{kj} being 1 and its expectation are both equal to $\pi_{kj}^{(1)}$. The total sample size for demographic stratum l in stratum k can be expressed as

$$n_{k+l} = \sum_{j \in s_l} n_{kjl} = \frac{1}{m_k} \frac{n_{k+l}^*}{N_{k+l}} N_l \sum_{j \in s_l} \frac{N_{kjl}}{N_{kj}} = \frac{1}{m_k} \frac{n_{k+l}^*}{N_{k+l}} N_l \sum_{j=1}^{M_k} \frac{N_{kjl}}{N_{kj}} I_{kj}.$$

This is not exactly the desired sample size n_{k+l}^* , It will depend on which PSUs have been sampled at the first stage. However, n_{k+l}^* will be the average of all possible outcomes of the sample size, as can be demonstrated by taking the expectation:

$$En_{k+l} = \frac{1}{m_k} \frac{n_{k+l}^*}{N_{k+l}} N_l \sum_{j=1}^{M_k} \frac{N_{kjl}}{N_{kj}} EI_{kj} = \frac{1}{m_k} \frac{n_{k+l}^*}{N_{k+l}} N_l \sum_{j=1}^{M_k} \frac{N_{kjl}}{N_{kj}} m_k \frac{N_{kj}}{N_k} = n_{k+l}^*$$

APPENDIX B: PROOF OF OPTIMAL SAMPLE ALLOCATION IN SECTION 5.5

Total variance V of a sample mean in a two-stage design has the form

$$V = \frac{V^{(1)}}{m} + \frac{V^{(2)}}{m\bar{n}}$$

Given the cost function $C = c_0 + c_1 m + c_2 m\bar{n}$, minimise V . Use Lagrange multipliers:

$$(I) \quad \frac{\partial}{\partial m} (V - \lambda(C - c_0 - c_1 m - c_2 m\bar{n})) = -\frac{V^{(1)}}{m^2} - \frac{V^{(2)}}{m^2 \bar{n}} + \lambda(c_1 + c_2 \bar{n}) = 0$$

$$(II) \quad \frac{\partial}{\partial \bar{n}} (V - \lambda(C - c_0 - c_1 m - c_2 m\bar{n})) = -\frac{V^{(2)}}{m\bar{n}^2} + \lambda c_2 m = 0$$

(II) implies $\lambda = V^{(2)} / c_2 m \bar{n}^2$. Substitute for λ in (I) gives

$$-\frac{V^{(1)}}{m^2} - \frac{V^{(2)}}{m^2 \bar{n}} + \frac{V^{(2)}}{c_2 m \bar{n}^2} (c_1 + c_2 \bar{n}) = 0$$

Solving this equation for \bar{n} provides the result (3) in the box in section 5.5.

6 RECRUITMENT OF PARTICIPANTS TO HES

Liv Grøtvedt¹, Hanna Tolonen², Kari Kuulasmaa², Sidsel Graff-Iversen¹

¹Norwegian Public Health Institute, Oslo, Norway

²National Public Health Institute, Helsinki, Finland

This chapter provides some general recommendations on recruitment methods, whose importance lies in the fact that a high participation rate is fundamental if the generalised inferences based on HES results are to be valid.

6.1 RECORD OF ELIGIBILITY STATUS, CONTACT EFFORTS, CONTACT AND PARTICIPATION

For each person invited to participate in the HES, we recommend keeping a record on eligibility status, the number and type of contact attempts, participation (enrolment) status and the reasons for non-contact and non-participation [1, 2].

Eligibility status: whether a person belongs to the target population or not, and if not, the reason why. Persons who were sampled but who died or emigrated prior to the HES have a negative eligibility status; other groups may also not be eligible, depending on the definition of the target population.

Contacted person: has in one way or another been contacted by the survey administration, probably through the letter of invitation, a text message or e-mail, or has been contacted by phone or through a home visit. Ideally, it should be known whether or not each invited person has read the invitation. In practice, it must be assumed that a letter not returned to sender or a successfully sent e-mail or text message is a contact. If contacted, it should be recorded if the person participated, refused or dropped out after having agreed to participate. If the person refused, the reason should be noted, if this information can be obtained.

Non-contacted: invitation letter returned to the survey administration and other contact not possible or not successful.

Participant (respondent): a person who has at least one valid examination measurement, such as height and weight, in addition to some questionnaire results.

Non-participant (non-respondent): refused or otherwise did not participate after the invitation was assumed to have been received or other contact was established.

Contact rate: the proportion of selected persons (of the total sample) who received the letter of invitation.

Enrolment rate: the proportion of persons contacted who actually participated in the survey.

Overall sample participation rate (response rate): the product of the contact rate and the enrolment rate.

Participation rate: participants/gross sample minus not eligible (deceased, moved out of area or otherwise defined as not in the target population).

The denominator of the contact rate, response rate and participation rate should not include persons who were selected for HES but in retrospect did not belong to the target population [i.e., were over-coverage, died, moved out of the primary sampling unit (PSU), emigrated or were defined as non-target population in the survey protocol]. Persons who were temporarily absent during the survey period because of work, studies, tourism, non-permanent hospitalisation or for other unknown reasons should be included in the denominator, as they are part of the target population.

6.1.1 RECOMMENDATIONS

1. For each invited person, precise record should be kept on eligibility status, number and type of contact attempts and participation status.
2. If possible, reasons for non-contact and non-participation should be recorded.
3. When calculating the participation rate (response rate), the denominator should not include persons who were selected for HES but in retrospect did not belong to the target population (not eligible: died, emigrated etc.)

6.2 RECRUITMENT (ENROLMENT) METHODS

Recruitment efforts should be geared towards obtaining the highest possible participation rate and at least a 70% participation rate both overall and in subgroups for which valid information is needed. It is important to obtain a high participation rate primarily as response to the first contact, so that there is an opportunity to reach a high final participation rate; a successful first contact, without the need for additional attempts, saves costs.

The strategy and methods for recruitment have to be determined by the individual country based on national and regional feasibility and legislation, the survey budget, and cultural norms. What is “perfect” in one setting may not be practical or provide the best results in another. The recommendations provided here are based on the literature and on the statements of national experts.

6.2.1 PREPARATIONS PRIOR TO THE SURVEY

6.2.1.1 INFORMATION

Who should be informed?

- National and local health authorities and health professionals should be informed about the survey in advance.
- Information about the survey should be provided to the local government, ensuring the community’s understanding and support.
- The persons selected to participate in the survey may be sent an announcement letter prior to the invitation.

How should the information be provided?

- The announcement letter and the invitation should include a leaflet with all of the important information about the survey.
- An internet homepage with information should be created; if possible, the homepage should allow appointments to be made and provide the number of a toll-free telephone line.

What should the information contain?

- The information should explain why HESs are important for improving public health, what measurements are taken, why an invited person should participate, and why an invited person cannot be replaced by someone else.
- The importance of each measurement for the individual participant and the population (regional/ national) should be explained. Feedback on the personal examination and the test results should be offered. Suggested phrases include “free examination”, “free to discuss your findings with the survey medical officer”, and “an opportunity to do an important community service”.
- The informed consent form should mention that the participants’ rights are guaranteed. The form may ask for specific consent for individual measurements, so that participants can choose whether or not they want to undergo certain examinations.
- The amount of time required for participation should be specified.
- The importance of the participation of every individual, whether extremely healthy, unhealthy or somewhere in between, should be emphasised.

Format:

- All written materials should be as concise as possible and “user friendly” (i.e., easy to understand and fill in, even by participants with slight linguistic or cognitive impairment; colour could also be used).
- The material should look professional and be easily distinguishable from advertising materials.
- If necessary, the material could be translated into other languages.
- Depending on the age of the participants (i.e., younger or older), the format (including the size of the letters), the length, and the wording of the written materials and the questionnaire could be modified.

- All written materials should provide a link to the internet site and the number to a toll-free telephone line in case of questions.

Information from non-participants:

- An invitation to non-participants, including a non-participant questionnaire (see enclosures to this chapter), should be prepared for collecting some health-related knowledge that can be used to evaluate the HES results.

6.2.1.2 SURVEY PERSONNEL

- The selection of competent and motivated personnel is of utmost importance.
- Sufficient training must be provided to the survey personnel for all tasks, including how to treat participants in a professional, friendly, respectful and caring manner.
- The personnel responsible for recruitment may be offered a bonus for high response rates in districts or age groups where participation is expected to be lower.

6.2.1.3 ORGANISATION AND PARTNERSHIP FOR ENHANCING PARTICIPATION

- For persons invited to participate, in addition to scheduled appointments, drop-in participation should be considered.
- The use of compensation or small “thank-you gifts” for participation (financial or other) may be considered. For example, a project-logo pen with the internet address and phone number may be sent with the letter of invitation: sending such items together with the invitation seems to be more effective than promising to offer the item when meeting with the participant.
- The employers of the participants should be encouraged to allow their employees to participate in the survey during working hours.
- Cooperation with regional or local hospitals, non-governmental organisations, research centres and universities may increase the interest in participation.

- Home visits may be used as the primary survey site or as an option for persons who are otherwise unable or unwilling to participate (see Chapter 4.2.2.1).

6.2.1.4 PLANNING A MASS MEDIA STRATEGY

- A media strategy should include establishing and organising contact with relevant national, regional, and local media: Who contacts whom? On what issues? And how? This should be planned for each stage of the project.
- A media strategy should include identifying a media contact for unforeseen occurrences or negative press coverage.
- It may be a good idea to involve national and regional authorities in the mass media strategy, although they are not directly involved in the survey organisation.

6.2.2 AROUND THE TIME OF THE SURVEY

6.2.2.1 MASS MEDIA CONTACT

It is of particular importance that the survey be covered by the mass media during the week that the invitation letters are sent out.

6.2.2.2 RE-INVITATIONS TO THOSE NOT PARTICIPATING BY THE FIRST INVITATION

Regardless of the primary response rate, even if it is 70-80%, 1-3 re-contacts are recommended.

In all types of survey, incorrect addresses and no telephone contact are well known problems. Many of the persons who do not show up after the first invitation probably simply did not receive it. Some resources could be used to trace these persons, perhaps by applying supplementary frames. For young adults, who are most likely to change their address often, the use of student lists may be helpful.

The re-invitations may consist of a letter (with or without the questionnaire), phone calls, or home visits, depending on cultural acceptability. Among persons below a certain age, the most suitable means of contact may be a mobile phone, whereas among older persons home telephones and home visits may be more suitable. A personal

approach, using a telephone/mobile telephone, home visit or e-mail, may be more effective than a second letter of invitation; this also allows the scheduling of the appointment to be “tailored”.

The heading, introduction and the specific person signing the invitation letter have been found to influence participation and should be considered. Changes may be made with respect to the first invitation. The hours in which the survey is performed and measurements are taken can be made more flexible (early mornings, evenings, weekends, possibility for drop-in for the invited persons). Reimbursements or small gifts other than those used in the first invitation should be considered. For persons who did not participate after the first invitation, home visits can be offered.

Substitution of a non-contact with, for example, a neighbour, is not acceptable (see also Section 5.4, Sampling techniques). Obtaining information from proxies for the interview component of the HES is not acceptable (e.g., information on health issues provided by the spouse for a person working abroad). However, a non-participant questionnaire may be answered by a proxy if the selected person cannot be reached (see Attachments A and B in this chapter).

6.2.3 RECOMMENDATIONS

1. All written materials, including the survey website, should be informative, user-friendly, appealing and professional looking.
2. Health authorities, healthcare providers and local governments should be informed of the survey prior to providing public information and sending the invitations to the selected persons.
3. The public should be provided with information by the mass media around the same time that the invitations are sent.
4. The first contact with the selected candidates should be a letter of invitation, which should include detailed information. A suggested appointment time and a telephone number for re-scheduling should be provided in the invitation letter.
5. Providing compensation or small gifts for participation should be considered.
6. Participation should be facilitated through flexibility: re-scheduling of and appointment, prolonged opening hours, possibility for selected persons to drop-in without an appointment, easy access to the examination site, home visits.

7. The field personnel should be trained to be professional, polite, interested and friendly when meeting with participants.
8. At least one re-invitation should be made, even if the participation rate is high, and at least two re-invitations when the initial participation rate is lower than 70%.
9. For re-invitations, the accuracy and the recentness of the contact information must be checked.

6.3 NON-RESPONSE ANALYSIS

A high participation rate is fundamental for drawing valid conclusions for entire populations based on the results of the HES [3-5]. The different measurements and questionnaire items included in the HES will vary somewhat in terms of the risk of selection bias. Evaluations of this problem have led to the agreement that participation rates of 70 % or higher should be achieved in all countries [6]; ideally, the participation rate should exceed 70 %.

Even when the participation rate is high, it is important to collect information on non-participants to evaluate potential biases in estimates [7-9]. Two questionnaires for non-participants or proxy information based on EHIS [10] are developed.

Non-participants should be asked to provide the information reported in the short questionnaire in Attachment A or the longer version in Attachment B, by either sending them the paper or electronic form or filling out the questionnaire during a telephone interview or home visit. If the invited person is not available (by phone, e-mail or other means), proxy information may be used for completing the short non-participant questionnaire. In some countries, register information can be used for this purpose, in addition to the questionnaire.

6.3.1 RECOMMENDATIONS

1. Soon after the survey, a short questionnaire on health and risk factors should be offered to the non-participants by mail, telephone, e-mail or home visit.
2. In addition to the non-participant questionnaire, if possible, the sampling frame should, be used to compare participants and non-participants by age, sex, region of residence, marital status and other demographic factors that are available for all of the invited persons.

3. If possible, the invitation file should be linked to more directly health related data such as hospitalisation or disability benefits or to information on education and income.

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ATTACHMENT A: NON-PARTICIPANT FORM (SHORT VERSION)**Reference number:** |_|_|_|_|_|_|_|_|**Date filling out (day, month, year):** |_|_|_|_|_|_|_|_|_|_|_|_|_|_|**Date of birth: Day, month, year:** |_|_|_|_|_|_|_|_|_|_|_|_|_|_|**Sex**☐ male☐ female**What is your legal marital status? (HH.5 in EHIS)**☐ single, that is never married☐ married (including registered partnership)☐ widowed and not remarried☐ or divorced and not remarried (including legally separated and dissolved registered partnership)?**What is the highest education leaving certificate, diploma or education degree you have obtained? Please include any vocational training. (HH.7 in EHIS)**☐ primary education (or less)☐ secondary education☐ post-secondary but non-tertiary☐ university or college (first or second stage of tertiary education)**Do you smoke at all nowadays? (SK.1 in EHIS)**☐ yes, daily☐ yes, occasionally☐ not at all**Reason for non-participation (from MONICA)**☐ not possible to contact, i.e. not found at the address☐ temporarily out from the area during the actual survey☐ not able to respond due to medical reasons (hospitalized or too ill to respond during the survey)

- ☐ not interested in additional medical assessment
- ☐ other refusal
- ☐ insufficient data

Non-respondent information obtained by (from MONICA)

- ☐ home visit
- ☐ postal questionnaire
- ☐ telephone call
- ☐ visit to hospital
- ☐ other
- ☐ information not available

Person giving information to fill out this form (from MONICA)

- ☐ person selected into the survey him/herself
- ☐ a family member of the person selected into the survey
- ☐ other

ATTACHMENT B: NON-PARTICIPANT FORM (LONG VERSION)**Reference number:** |_|_|_|_|_|_|_|_|**Date filling out (day, month, year):** |_|_|_|_|_|_|_|_|_|_|_|_|_|_|**Date of birth: Day, month, year:** |_|_|_|_|_|_|_|_|_|_|_|_|_|_|**Sex**

- ☐ male
- ☐ female

What is your legal marital status? (HH.5 in EHIS)

- ☐ single, that is, never married
- ☐ married (including registered partnership)
- ☐ widowed and not remarried
- ☐ or divorced and not remarried (including legally separated and dissolved registered partnership)?

What is the highest education leaving certificate, diploma or education degree you have obtained? Please include any vocational training. (HH.7 in EHIS)

- ☐ no formal education or below
- ☐ primary education
- ☐ lower secondary education
- ☐ upper secondary education
- ☐ post-secondary but non-tertiary education
- ☐ first stage of tertiary education
- ☐ second stage of tertiary education

Do you smoke at all nowadays? (SK.1 in EHIS)

- ☐ yes, daily
- ☐ yes, occasionally
- ☐ not at all

Have you had this disease condition in the past 12 months? (part of HS.6. in EHIS)

High blood pressure (hypertension)

- ☐ yes
- ☐ no
- ☐ don't know
- ☐ refusal

During the past two weeks, have you used any medicines (including dietary supplements such as herbal medicines or vitamins) that were prescribed or recommended for you by a doctor – (for women: includes also contraceptive pills or other hormones)? (MD.1 in EHIS)

- ☐ yes
- ☐ no
- ☐ don't know
- ☐ refusal

Where they medicines for ...? (part of MD.2 in EHIS)

High blood pressure

- ☐ yes
- ☐ no
- ☐ don't know
- ☐ refusal

How tall are you without shoes? (BMI.1 in EHIS)

|_|_|_| cm

- ☐ don't know
- ☐ refusal

How much do you weigh without clothes and shoes? (BMI.2 in EHIS)

|_|_|_| kg

- ☐ don't know
- ☐ refusal

Reason for non-participation (from MONICA)

- ☐ not possible to contact, i.e. not found at the address
- ☐ temporarily out from the area during the actual survey
- ☐ not able to respond due to medical reasons (hospitalized or too ill to respond during the survey)
- ☐ not interested in additional medical assessment
- ☐ other refusal
- ☐ insufficient data

Non-respondent information obtained by (from MONICA)

- ☐ home visit
- ☐ postal questionnaire
- ☐ telephone call
- ☐ visit to hospital
- ☐ other
- ☐ information not available

Person giving information to fill out this form (from MONICA)

- ☐ person selected into the survey him/herself
- ☐ other

7 LEGAL AND ETHICAL ISSUES

Susanna Conti¹, Grazia Rago¹, Mark Kanieff¹

¹Italian National Institute of Public Health, Rome, Italy

7.1 INTRODUCTION

In conducting research involving humans, two of the fundamental concerns, in addition to the ethical conduct of the research itself, are the safeguarding of the participant's privacy and the acquiring of his/her informed consent. Based on a survey of how Member States have addressed these concerns in the health examination surveys (HES) or similar studies that they have conducted to date, we have developed a series of recommendations to be followed when performing a HES in Europe. In particular, herein we provide some general recommendations on the ethical conduct of a HES, with specific reference to the safeguarding of privacy (or "data protection"); we also provide a model of an informed consent form, which is intended as a guide for creating such a form for use in HESs in Europe.

7.2 GENERAL RECOMMENDATIONS ON THE ETHICAL CONDUCT OF A HES

Any type of research on human subjects must obviously be conducted according to ethical standards, which are mandated by specific legislation, examples of which include: i) acts regulating the status and/or rights of patients; ii) medical research acts; iii) other national ethical principles of research involving humans; and iv) international biomedical research guidelines.

However, this legislation varies by individual country. Thus when planning a HES, it must be ensured that the study protocol comply with the given country's specific legislation. Internationally, the Declaration of Helsinki, "Ethical Principles for Medical Research Involving Human Subjects", is considered to be the pillar of ethical standards.

Other important reference documents include the Belmont Report (“Ethical Principles and Guidelines for the Protection of Human Subjects of Research”) and two important acts of the Council of Europe: the Recommendation of the Committee of Ministers No. R(90) 3 concerning medical research on human beings and the Oviedo Convention on Human Rights and Biomedicine.

7.3 ETHICS COMMITTEE

That research is conducted following appropriate ethical standards is the responsibility of an ethics committee, which can be local, regional, or national. This committee must approve all aspects of the research, including the performance of the study itself, informed consent, the safeguarding of privacy, and the use of data and biological materials, both for the research being conducted and any future purposes. When planning a HES, it should be considered that obtaining approval from the ethics committee may take some time, even months.

7.4 THE SAFEGUARDING OF PRIVACY, DATA PROTECTION AND SUBJECTS’ RIGHTS

As stated in the Declaration of Helsinki, “...Every precaution should be taken to respect the privacy of the subject [and] the confidentiality of the patient’s information...”, which has become increasingly important, given the progress made in information technology and the consequent ease of access to data. That privacy is safeguarded is ensured through legislation (generally a “Data Protection Act”).

Given that performing a HES includes collecting a particular type of personal data (i.e., sensitive data regarding health), the HES protocol should comply with the given country’s Data Protection Act and cover all aspects of data protection, in particular: access to data, the exchange of data, record linkage, and anonymisation procedures. In Europe, the most important document regarding data protection is: “Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data”.

7.5 INFORMED CONSENT

Before performing any kind of research involving humans, informed consent must be obtained, which goes beyond merely getting an individual to sign a written form. It is a process of communication between an individual and the healthcare professional who

is conducting the study, with the goal of ensuring that the individual fully understands the scopes of the study, the methods adopted, and how the data will be used. This communication process is both an ethical and a legal obligation. The concept of consent is relevant to both the performance of the study itself and the protection of the participant's privacy.

Below is provided a model of an informed consent form, to be used as a reference for the forms used in European HESs. The model includes an introduction which explains its purpose and provides recommendations for those who will be responsible for this aspect of the HES.

7.6 RECOMMENDATIONS FOR CREATING AN INFORMED CONSENT FORM

Before performing any kind of research involving humans, informed consent must be obtained, which goes beyond merely getting an individual to sign a written consent form. It is a process of communication between an individual and the healthcare professional who is conducting the study, with the goal of ensuring that the individual fully understands the scopes of the study, the methods adopted, and how the data will be used. This communication process is both an ethical and a legal obligation. The concept of consent is relevant to both the performance of the study itself and protecting the privacy of the individual.

This document is intended to help you to create an informed consent form for the HES in your country. If you feel that another format would be more suited to your HES, then you are free to make any changes deemed necessary. For example, in the present form, the information provided to the candidate and the candidate's personal data and signature are provided on the same form; however, it is also possible to create two separate documents: one containing the information on the HES (referred to as an "information notice" or "information letter") and a separate document with the candidate's data and signature (the actual "informed consent form"). In general, the longer the information notice the shorter the informed consent form. One of the advantages to having two separate documents is that the information notice can be provided to candidates some time before the informed consent form, so that they have sufficient time to understand the implications of participation. Another example is that, in the present form, candidates are asked to provide a single signature which indicates consent to participate in all parts of the study. However, some countries may want to request that the candidate provide a separate consent and signature for each individual activity that he/she will undergo (e.g., blood taking, linking of data to other databases). Many of the questions on this form are followed by a comment that provides

suggestions or considerations which may help you in adapting the form for use in your HES.

Given that the ultimate goal is to ensure that participants are truly informed, the information provided must be complete and clear. You should thus use terminology that is simple and easy to understand, avoiding scientific terms when possible. Moreover, excessively complex or long descriptions can confuse or intimidate study candidates. You may also want to consider such measures as: providing the study candidates with the information notice before requesting informed consent (as mentioned above); setting up a telephone help-line for candidates; and translating the form into other languages.

The protocol for conducting the HES in your country, including the informed consent form, will have to be approved by your national, regional, or local ethics committee, so as to ensure that it complies with national legislation and ethical standards. Many of the sections in this form may have to be modified to be consistent with the legislation in your country (e.g., that regarding access to data and storage of samples in biobanks).

If you require any assistance or additional information, you can contact the individual responsible for coordinating the legal and ethical aspects of the European HES.

7.7 MODEL OF AN INFORMED CONSENT FORM TO BE USED IN EUROPEAN HES

To the study candidate.

You are eligible to take part in a National Health Examination Survey (or “HES”).
[Comment: If the HES includes minors or persons not capable of providing informed consent, the word “you” should be substituted with “your child” or “your legal ward” or with the actual name of the study participant] A HES is a study carried out for obtaining information on general health by interviewing individuals and measuring certain indicators that can be important to health, such as weight, blood pressure, and cholesterol level. This information is used to acquire knowledge on the health status of the population, which can be important in promoting and improving the health of all.

The HES is being conducted by *[specify name of organization conducting the HES in your country]* among a sample of *[specify expected number of participants]* individuals in *[specify study area, such as the town or province]*.

[Comment: Information on health concerns that are important in the specific country and for which a HES could be beneficial can be added here. For example “In

Italy, obesity is becoming an increasingly important health concern, yet there is little information on what percentage of the population can be considered as obese.” If the candidate feels that the study would be socially useful, then the chances of him/her participating could increase.]

Your name was chosen from among *[specify source of the person’s name and the area to which it refers]* *[Comment: This sentence should specify how the individual was chosen (e.g., from electoral rolls, social insurance registers, population registers), so that he/she is aware of how the research personnel obtained his/her name.]*

All aspects of this study have been approved by the Ethics Committee of the...*[specify the name or level of the ethics committee (e.g., France’s National Ethics Committee)]*.

The present form includes important information about the study and a description of what will be asked of you if you decide to participate. In order to participate, you will need to carefully read and sign this form. If any part of this form is not clear to you, you can contact the researchers conducting the study (see information below). *[Comment: The wording of this sentence may change according to who is available for providing clarifications or depending on whether or not information aids, such as telephone help-lines, are provided.]*

Your participation is important to us, but please be assured that it is voluntary, that you may leave the study at any time, and that your data will be kept confidential.

What will be asked of me if I decide to participate?

If you decide to participate in the HES, you will be contacted *[Comment: If known, the name of the person who will contact the participant could be put here, or their profession (e.g., “...a nurse will contact you...”)]* to schedule a visit at... *[Comment: The site where the study activities will be performed should also be specified (e.g., in the participant’s home, a mobile clinic)]*. During this visit, you will be asked to answer questions on ...*[Comment: Specify the topics that the questions will cover. If an interview is not conducted (e.g., if a self-administered questionnaire is used), the wording of this section should be modified accordingly)]*. Measurements of your height, weight, and blood pressure will be taken; a blood/urine/saliva sample will also be taken *[Comment: If the HES comprises additional modules, then modify accordingly]*. The sample will be tested for ... *[Comment: To be modified in accordance with the specific objectives of the HES]* and other health-related indicators *[Comment: It is important to assure study candidates that the samples will not be used to test for*

other purposes (e.g., HIV testing, drug testing); examples could be provided. If DNA testing is performed, this should be declared].

How much of my time will be needed to take part in this study?

To perform the interview and collect the samples needed for the study, approximately __ hours will be needed. These activities will be performed in just one visit. *[Comment: Specify the total time in hours, number of visits, amount of time per visit. This is an important consideration for candidates in deciding whether or not to participate, in that an excessive amount of time could discourage participation. However, the researchers should not underestimate the time needed.]*

Are there any health risks to participating in this study?

The taking of a blood sample may pose a minimal risk. *[Comment: Given that the risk associated with the taking of blood samples is minimal, this section can be eliminated. However, if any activities that may pose a risk are added to your HES, the potential risks must be disclosed. A related issue is the risk of the participant's having an accident while the HES measurements are being taken (e.g., falling and injuring oneself during the walking speed test). In planning a HES, how such incidents will be addressed (e.g., providing insurance coverage for the duration of the HES) should be taken into consideration, and any information regarding this issue should be included on this form].*

Will I be paid or given anything for taking part in this study?

[Comment: If no compensation is to be provided, then it is possible to write "No. You will not be paid for taking part in this study." or to eliminate this question. If instead it is provided, the description of compensation must be clear. Payment or other forms of incentive may not be allowed in certain countries].

Would you like to receive the results of the tests performed on the samples taken from you?

Yes ☐

No ☐

[Comment: It is assumed that in the HES no information that could be potentially upsetting to participants will be collected (e.g., HIV test results), though it should nonetheless be considered whether or not the participant could be upset by such information as, for example, obesity. If the participant's general practitioner is involved in collecting information for the study and is responsible for providing the results to the participant, then this should be specified. It may also be a good idea to specify an approximate time frame for providing the results (e.g., "The results of the tests will be provided to you in approximately 6 months").].

Who else will be provided with, or have access to, my data?

The data collected for this study will be used by the *[specify name of institution conducting the HES]* for the purposes of studying health-related issues. These data will also be provided to other institutes collaborating on the study, yet no information that can be used to identify you will be provided to these institutions. *[Comment: Given that data protection laws may vary by specific country, the entities that will have access to data may differ. For example, in some countries it may be legal to provide data on individuals to general practitioners or insurance companies. It is important that the candidate be aware of who will have access to his/her data.]*

Your data will also be stored in a computer database at *[specify name of institution conducting the HES]*, which can only be accessed by the researchers conducting the study. The data will also be combined with data from the HES conducted in other European countries in a centralized database.

The data may also be combined (or "linked") with other data from different sources *[Comment: If you already know which databases will be linked, then this information could be provided here.]* For example, if you have a specific health condition and the data on your condition have been recorded in another database, then the researchers may combine these data with the data collected in the present survey, so as to study causes and relationships for certain health conditions, which is important in determining the population's health status.

Please be assured that anyone with access to data, other than the institution performing this study, will not be provided with your name or address or any other information that can be used to identify you.

The results of this study could be published in an article, presented at a scientific meeting, or placed on a specific website, but they would not include any information that would let others know who you are.

How will my data be kept confidential and my privacy be protected?

[Comment: Describe procedures that will be followed to keep subject information and specimens secure and confidential. For example: “Records will be kept in a separate research file that does not include names or other information that could be used by anyone but the researchers to identify you.”]

The information collected will be kept strictly confidential. In *[specify country]*, data confidentiality is guaranteed by law *[specify data protection act]*. In Europe, it is guaranteed by “Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data”.

In any case, your name or any data that could possibly be used to identify you will only be known to the *[specify institution conducting the HES]*.

At any point during or after the study, if you are concerned about a possible violation of your privacy, you can contact ...*[Comment: If there is an organisation in your country for reporting violations of privacy, complete contact information should be provided here.]*

What happens to information about me after the study is over or if I withdraw from the study?

As mentioned, your data may be used for other studies of health-related issues. However, these data will be kept strictly confidential at all times. If you withdraw from the study, it may be decided that the information collected up to that time will be retained *[Comment: Whether or not data from persons withdrawing from the study must be discarded may depend on the specific legislation in your country.]* Nonetheless, if you wish all of your data to be eliminated, you can request that this be done.

What will happen to my blood/saliva/urine samples after the study is over?

Your samples may be stored at the *[Specify name of organization conducting the HES in your country]* or in what is referred to as a “biobank” (that is, a storage space for biological materials) and used at a later time for other health studies. However, as mentioned above, these samples will not be tested for... *[specify tests NOT to be performed; see comment above]*. *[Comment: In your country, there may be legal limitations regarding the storage (including duration) and use of biological materials].*

After this study is complete, we may want to contact you for additional studies; would you be willing to be contacted?

Yes ☐

No ☐

CONTACT INFORMATION

Who can I contact about this study?

For any questions or concerns, you can contact the researcher(s) listed below.
[Comment: It is important that the participant be provided with the possibility to speak with someone for any questions or doubts that he/she may have. Not only can this be reassuring for the study candidate or participant, but it might also increase the participation rate.]

Principal Investigator *[specify name of Principal Investigator]* *[Comment: The person available for providing clarifications may change according to how your HES is organized.]* :

Mailing Address:

Telephone:

SIGNATURES

Participant:

I understand the information printed on this form. I understand that if I have more questions or concerns about the study or my participation, I may contact the person(s) listed above.

Date: _____

Signature of participant: _____

Name (Print legal name): _____

Participant ID: _____

Date of Birth: _____

Legal Representative (if applicable) [Comment: If persons unable to fully consent for themselves are included in the HES, this section should be filled in by the person's legal guardians.]

Date: _____

Signature of person legally authorized to give consent:

Name (Print name): _____

Check relationship to participant:

☐ Parent

☐ Spouse

☐ Son/Daughter

☐ Sibling

☐ Legal Guardian

☐ Other: _____

Reason participant is unable to sign for self:

Person receiving the informed consent:

I have received the informed consent of (name of participant).

Date: _____

Signature of person receiving informed consent: _____

Name (Print legal name): _____

8 MEASUREMENT PROTOCOLS

Lucie Viet¹, Hanna Tolonen², Sanna Natunen², Kari Kuulasmaa², Monique Verschuren¹

¹National Institute for Public Health and the Environment, Bilthoven, the Netherlands

²National Public Health Institute, Helsinki, Finland

8.1 INTRODUCTION

In this chapter, recommended measurement protocols are described. The recommendations are based mostly on the review of the experience from earlier HESs and on recent developments in HES methods, which the FEHES Project has prepared and published separately [1]. For the risk factors of major chronic diseases, the recommended measurement protocols are similar to those of the European Health Risk Monitoring project (EHRM) [2], with updates based on recent technological developments. The protocol for automated blood pressure measurement is taken from the recommendations of the World Health Organisation's STEPwise approach to Surveillance (STEPS) [3].

For each recommended measurement, we describe the relevance of the measure, the standardized equipment, the means of performing and recording the measure, the exclusion criteria and the quality control measures. This chapter includes currently standard measurement protocols for the core examination measurements, which are expected from all HES, and for a number of optional measurements, primarily measurements of functional capacity in the elderly.

8.2 HEIGHT

Age: Height can be measured in participants (who can stand) aged 4 years and older.

Exclusion criteria: Height is not measured for wheelchair bound persons, persons who have difficulty standing straight, or persons with a hairstyle that prevents proper use of the equipment (e.g. Afro or Mowhawk); for the latter group, self-reported height is acceptable, and that it is self-reported must be recorded on the data collection form.

Time of measurement: The measurement of height will take about 3 minutes.

8.2.1 EQUIPMENT

- The most reliable device for measuring height is the portable stadiometer (and a fixed stadiometer). This device can be used in different settings, including mobile units, and it can be adjusted to surfaces that are not completely flat.
- Carpenter's level.
- Calibrated length rods of 150 cm and 200 cm.

8.2.2 MEASUREMENT PROTOCOL

Setting up the measurement site

For measuring height with the stadiometer, the height rule is taped vertically to the hard flat wall surface with the base at floor level. A carpenter's level is used to check the vertical placement of the rule.

The floor surface next to the height rule must be hard. If no such floor is available, a hard wooden platform should be placed under the base of the height rule.

Calibration of height rule

At the beginning and end of each examination day, the height rule should be checked with standardized rods and corrected if the error is greater than 2 mm. The results of the checking and recalibrations are recorded in the log book.

Protocol for measuring height

1. Participants are asked to remove their shoes, heavy outer garments, and hair ornaments and head dress.
2. The participant is asked to stand with his/her back to the height rule. The back of the head, back, buttocks, calves and heels should be touching the stadiometer, feet together. The top of the external auditory meatus (ear canal) should be level with the inferior margin of the bony orbit (cheek bone). The participant is asked to look straight ahead.
3. The head piece of the stadiometer or the sliding part of the measuring rod is lowered so that the hair is pressed flat.
4. Height is recorded to the resolution of the height rule (i.e., nearest millimeter/half a centimeter). If the participant is taller than the measurer, the measurer should stand on a platform so that he/she can properly read the height rule.
5. If the person is taller than the maximum height of the stadiometer, the self reported height is acceptable and recorded on the data collection form.
6. If a participant is excluded from height measurement, the reason should be recorded on the data collection form (see Chapter 8.2.3).

8.2.3 RECORDING FORM

From height measurement, at least following information should be recorded:

Participant's identification code:	_ _ _ _ _ _ _
Measurer's identification code:	_ _ _
Date of the measurement (dd.mm.yyyy):	_ _ _ . _ _ _ _ _ _
Height (cm)	_ _ _ _ _ _ _

Reason why height was not measured	<input type="checkbox"/> Hairstyle/ head gear <input type="checkbox"/> Wheelchair bound <input type="checkbox"/> Unsteady stand <input type="checkbox"/> Height exceeds upper limit of stadiometer (upper limit of the stadiometer: <input type="text"/> <input type="text"/> <input type="text"/> cm) <input type="checkbox"/> Refusal <input type="checkbox"/> Other, specify: _____
If no height measurement, self-reported height (cm):	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Special conditions, if any:	_____

8.2.4 QUALITY CONTROL

8.2.4.1 DURING THE SURVEY

Quality control measures during the survey involve:

- checking and re-calibration of equipment in regular intervals and results should be recorded to the log book;
 - monitoring of the performance of the measurers by checking routinely for each measurer
 - the distribution of terminal digit of the measurements,
 - mean and standard deviation of the measurements,
 - recordings of the reasons why measurements were not performed, and
 - daily work load (number of measurements per day).
- in case of extended survey, a refresher sessions for all measurers every three months,
- surprise audit visits to the examination sites to observe the measurers.

8.2.4.2 AFTER THE SURVEY

From the pooled data of all measurers, following issues should be checked:

- item response rates, and
- distribution of terminal digits.

8.3 WEIGHT

Age: Weight can be measured in participants aged 4 years and older.

Exclusion criteria: Weight is not measured for wheelchair bound individuals or persons who have difficulty standing steady; for the latter group, self-reported weight is acceptable and it must be specified that it is self-reported in the the collection form.

Time of measurement: The measurement of weight will take about 3 minutes.

8.3.1 EQUIPMENT

- Balanced beam scale or an electronic scale that has been issued an EC type-examination certificate for medical use. This scale can be calibrated.
- Several calibrated weights (e.g. 10 kg or 20 kg each) that can be combined to give test weights between 50 kg and 100 kg.

8.3.2 MEASUREMENT PROTOCOL

Setting up the measurement site

The scale should be placed on a hard floor surface (not on a floor which is carpeted or otherwise covered with soft material). If there is no such floor available, a hard wooden platform should be placed under the scale. A carpenter's level should be used to verify that the surface on which the scale is placed is horizontal.

Calibration of scale

Calibration should be done at the beginning and end of each examination day.

The scale is checked using the standardized weights and calibration is corrected if the error is greater than 0.2 kg. The results of the checking and the recalibrations are

recorded in a log book. The balanced beam scale is balanced with both sliding weights at zero and the balance bar aligned. To calibrate an electronic scale, follow the instructions of the specific scale. Note that the reading of an electronic scale depends on the gravity in each location. Therefore its calibration is particularly important whenever a new examination site is set up.

Protocol for measuring weight

- Participants are asked to remove their heavy outer garments (jacket, coat, trousers, skirts, etc.) and shoes. If they refuse to remove their trousers or skirt, at least make them empty their pockets and record the fact in the data collection form (see Textbox 8.2).
- The participant stands in the centre of the platform, weight distributed evenly on both feet (standing off-centre may affect measurements).
- The weights are moved until the beam balances (the arrows are aligned) (for the balanced beam scale only).
- If the person's weight exceeds the maximum of the scale, the self-recorded weight is acceptable and recorded on the collection form.
- If the participant report that she is pregnant, the weight before the pregnancy should be asked and noted on the collection form under self-reported weight.
- The weight is recorded to the resolution of the scale (the nearest 0.1 kg or 0.2 kg). (See Chapter 8.3.3)

8.3.3 RECORDING FORM

From weight measurement, at least following information should be recorded:

Participant's identification code:	_ _ _ _ _ _ _
Measurer's identification code:	_ _ _
Date of the measurement (dd.mm.yyyy):	_ _ _ . _ _ _ _ _ _
Weight (kg)	_ _ _ _ _ _ _

Reason why weight was not measured	<input type="checkbox"/> Wheelchair bound <input type="checkbox"/> Unsteady stand <input type="checkbox"/> Weigh exceeds upper limit of scale (upper limit of the scale: <input type="text"/> <input type="text"/> <input type="text"/> kg) <input type="checkbox"/> Refusal <input type="checkbox"/> Other, specify: _____
If no weight measurement, self-reported weight (kg):	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Special conditions, if any:	_____

8.3.4 QUALITY CONTROL

8.3.4.1 DURING THE SURVEY

Quality control measures during the survey involve:

- checking and re-calibration of equipment in regular intervals and results should be recorded to the log book;
 - monitoring of the performance of the measurers by checking routinely for each measurer
 - the distribution of terminal digit of the measurements,
 - the distribution of terminal digits for full kilograms,
 - mean and standard deviation of the measurements,
 - recordings of the reasons why measurements were not performed, and
 - daily work load (number of measurements per day).
- in case of extended survey, a refresher sessions for all measurers every three months,
- surprise audit visits to the examination sites to observe the measurers.

8.3.4.2 AFTER THE SURVEY

From the pooled data of all measurers, following issues should be checked:

- item response rates,
- distribution of terminal digits, and
- distribution of terminal digits for full kilograms.

8.4 WAIST AND HIP CIRCUMFERENCES

Age: The waist and hip circumference can be measured for participants aged 18 years and older.

Exclusion criteria: Waist and hip circumferences are not measured for persons who are wheelchair bound or have difficulty standing straight. If the participant is immobile or refuses to have his/her waist or hip circumference measured, this fact should be recorded on the data collection form (see Chapter 8.4.3). Self-reported waist or hip circumference is not acceptable. If the waist or hip circumference exceeds the length of the tape, this fact should be recorded on the data collection form, together with the maximum length of the tape.

Time of measurement: The measurement will take about 5 minutes.

8.4.1 EQUIPMENT

- Constant tension tape, not stretchable
- Full body length mirror with 10cm × 10cm grid lines
- Carpenter's level

8.4.2 MEASUREMENT PROTOCOL

Setting up the measurement site

A private area is necessary for this measurement. This could be a separate room or a screened-off area.

The full body length mirror is placed against the wall or, if it is a free-standing mirror, next to the spot where the measurement will be taken. Using the carpenter's level, it should be verified that the gridlines on the mirror are horizontal.

Checking the tape

The length of the measuring tape is checked with the calibrated length rod (usually the 150 cm one) at least once per month. If the measuring tape is stretched, it should be replaced

Protocol for measuring waist and hip circumferences

This measurement should be taken without clothing, that is, directly over the skin.

If this is not possible, the measurement may be taken over light clothing, recording this fact on the data collection form. It must not be taken over thick or bulky clothing, which must be removed. If the participant reports that she is pregnant, the measurement is not taken.

8.4.2.11 WAIST CIRCUMFERENCE

Position of waist circumference measurement

Waist circumference should be measured at a level midway between the lower rib margin and the iliac crest, with the tape wrapped around the body in a horizontal position.

Waist circumference measurement procedure

1. Participants are asked to remove their clothes, except for light underwear. If this is not possible, for example due to cultural reasons, the person should remove heavy outer garments, and this should be recorded on the data collection form; tight clothing, including the belts, should be loosened and the pockets emptied.
2. The measurer should stand at the side of the participant in order to have a clear view of the mirror.

3. Participants should be standing with their feet fairly close together (about 12-15 cm) with their weight equally distributed on each leg. Participants are asked to breathe normally; the reading of the measurement should be taken at the end of gentle exhaling. This will prevent subjects from contracting their abdominal muscles or from holding their breath.
4. The measuring tape is held firmly, ensuring its horizontal position. Use the grid lines on the mirror to verify that the tape position is horizontal all around the waist. The tape should be loose enough to allow the observer to place one finger between the tape and the subject's body.

Waist circumference exceeds the length of the tape

If the waist circumference exceeds the length of the tape, this fact should be recorded on the data collection form together with the maximum length of the tape. (See Chapter 8.4.3)

8.4.2.2 HIP CIRCUMFERENCE

Measurement of the hip circumference is the same as for waist circumference, except for the tape position. Hip circumference should be measured as the maximal circumference over the buttocks. The gridlines on the mirror are used to verify that the tape position is horizontal all around the body.

Hip circumference exceeds the length of the tape

If the hip circumference exceeds the length of the tape, this fact together with the maximum length of the tape, should be recorded on the data collection form (Chapter 8.4.3).

8.4.3 RECORDING FORM

From waist and hip circumference measurements, at least following information should be recorded:

Participant's identification code:	_ _ _ _ _ _ _
Measurer's identification code:	_ _ _
Date of the measurement (dd.mm.yyyy):	_ _ _ . _ _ _ . _ _ _ _

Waist circumference (cm)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Hip circumference (cm)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Reason why waist circumference was not measured	<input type="checkbox"/> Wheelchair bound <input type="checkbox"/> Unsteady stand <input type="checkbox"/> Circumference exceeds upper limit of tape (upper limit of the tape <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> cm) <input type="checkbox"/> Refusal <input type="checkbox"/> Other, specify: <hr/>
Reason why hip circumference was not measured	<input type="checkbox"/> Wheelchair bound <input type="checkbox"/> Unsteady stand <input type="checkbox"/> Circumference exceeds upper limit of tape (upper limit of the tape <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> cm) <input type="checkbox"/> Refusal <input type="checkbox"/> Other, specify: <hr/>
Measurement was done over:	<input type="checkbox"/> Light underwear <input type="checkbox"/> Normal clothes (without heavy garments) <input type="checkbox"/> Other, specify: <hr/>
Special conditions, if any:	<hr/>

8.4.4 QUALITY CONTROL

8.4.4.1 DURING THE SURVEY

Quality control measures during the survey involve:

- checking and re-calibration of equipment in regular intervals and results should be recorded to the log book;
- monitoring of the performance of the measurers by checking routinely for each measurer

- the distribution of terminal digit of the measurements,
 - mean and standard deviation of the measurements,
 - recordings of the reasons why measurements were not performed, and
 - daily work load (number of measurements per day).
- in case of extended survey, a refresher sessions for all measurers every three months,
 - surprise audit visits to the examination sites to observe the measurers.

8.4.4.2 AFTER THE SURVEY

From the pooled data of all measurers, following issues should be checked:

- item response rates, and
- distribution of terminal digits.

8.5 BLOOD PRESSURE

Traditionally, blood pressure has been measured using the mercury sphygmomanometer, and the 2002 EHRM recommendations are based on this device [2]. However, because of the toxicity of mercury, the mercury sphygmomanometers may be banned in the future, and alternative devices will need to be found. In some of the previous HESs, automated blood pressure measurement devices have been used. There are also a number of commercially available aneroid sphygmomanometers, yet we are not aware of any national HES in which they were used.

We describe the measurement protocol for both the mercury sphygmomanometer and the automated blood pressure measuring device. The preparation for taking the measurement is the same for the two devices, though the actual measurement protocol differs. Preparation for the measurement and the measurement protocol for the mercury sphygmomanometer follow the EHRM protocol, whereas the measurement protocol for the automated blood pressure measurement device follows the WHO STEPS protocol.

Age: The blood pressure can be measured for participants aged 18 years and older.

Exclusion criteria: None

Time of measurement: It will take 15 minutes to measure the blood pressure.

8.5.1 PREPARATION FOR THE MEASUREMENT

8.5.1.1 BASIC CONDITIONS

Before the blood pressure is measured, the following conditions should be met:

1. The subject should abstain from eating, drinking (except water), smoking, or taking drugs that affect blood pressure, one hour before measurement.
2. Because a full bladder affects blood pressure, it should be emptied.
3. The subject should not undergo painful procedures or perform exercise one hour before measurement.
4. The subject should sit quietly for about 5 minutes.
5. The subject should remove outer garments and all other tight clothing. Sleeves should be rolled up so that the upper right arm is bare. The remaining garments should not be constrictive, and the blood pressure cuff should not be placed over the garment.
6. Blood pressure should be measured in a quiet room with a comfortable temperature (the room temperature should be recorded).
7. The time of day should be recorded.
8. The person taking the actual measurement should be identified on data collection form.
9. Blood pressure measurement device(s) should be numbered and the number of the device be recorded.

8.5.1.2 POSITION OF THE SUBJECT

The subject should be in a sitting position so that the arm and back are supported. The subject's feet should be resting firmly on the floor, not dangling. If the subject's feet do not reach the floor, a platform should be used to support them. If the subject

cannot sit and the measurement is taken on supine posture, this should be recorded. If the blood pressure is measured using the left arm, this should be recorded on the data collection form (see Chapter 8.5.4)

8.5.1.3 POSITION OF THE ARM

The measurements should be made on the right arm whenever possible. If not possible (e.g., the arm has been amputated or has rashes, adhesive dressing, casts, open sores, hematomas, wounds, arterovenous shunt or any other intravenous access device), the left arm should be used, and this should be recorded on the data collection form (see Chapter 8.5.4).

The arm should be resting on the desk so that the antecubital fossa (a triangular cavity of the elbow joint that contains a tendon of the biceps, the medial nerve, and the brachial artery) is at the level of the heart and palm is facing up. To achieve this position, either the chair should be adjusted or the arm on the desk should be raised (e.g., by using a pillow). The subject must always feel comfortable.

8.5.1.4 SELECTION OF THE CUFF

The greatest circumference of the upper arm is measured using a non-elastic tape, with the arm relaxed and in the normal blood pressure measurement position (antecubital fossa at the level of the heart). The measurement should be read to the nearest centimetre and recorded (see Chapter 8.5.4).

Select the correct cuff for the arm circumference and record the size of the selected cuff. The width of the bladder of the cuff should be at least 40% of the arm circumference and the length of the bladder at least 80% of the arm circumference. In the EHRM protocol [2], instructions are provided on how to determine the correct arm circumference for the different cuff sizes, for example:

Arm circumference	Width of the bladder of the cuff
≤ 25 cm	8 cm
$25 \text{ cm} < \text{arm circumference} < 35$ cm	12 cm
≥ 35 cm	16 cm

The cuff should be placed on the arm so that its bottom edge is 2-3 cm above the antecubital fossa. The top edge of the cuff should not be restricted by clothing.

A set of 3-4 cuffs with different size should be available and special attention should be paid to using the proper cuff width in relation to arm size. The length of the bladder should be enough to encircle at least 75-80% of the arm, and the arm circumference should be measured midway between the axilla and the antecubital space of the upper arm, with the arm relaxed and in the normal blood pressure measurement position (antecubital fossa at the level of the heart), using a non-elastic tape. The measurement should be read to the nearest centimetre and recorded on the data collection form (see Chapter 8.5.4).

8.5.1.5 NUMBER OF MEASUREMENTS

Three measurements should be taken, one minute apart.

8.5.2 MERCURY SPHYGMOMANOMETER

The measurer should briefly describe the procedure to the subject. In particular, he or she should warn the subject of the minor discomfort caused by the inflation and deflation of the cuff and tell the subject that the measurement will be repeated three times.

8.5.2.1 EQUIPMENT

For blood pressure measurements, the following equipment is required:

- simple mercury sphygmomanometer;
- stethoscope;
- 3-4 cuffs;
- non-elastic measuring tape; and
- stopwatch.

8.5.2.2 MEASUREMENT PROTOCOL

The bell of the stethoscope should be used because it gives clearer sounds than the diaphragm.

1. The radial pulse is palpated and the pulse rate is counted for 30 seconds, measured by a digital wrist watch or one with a second hand.
2. Record 30-second pulse count and whether or not the pulse was regular.
3. The manometer should be placed so that the scale is at eye level and the column is perfectly vertical. The subject should not be able to see the column of the manometer.
4. Determining the peak inflation level:
 - i. The mercury column has to be at 0 level.
 - ii. The subject's radial pulse is again palpated.
 - iii. The cuff is inflated and the level of the top of the meniscus of the mercury column is noted at the point when the radial pulse disappears. The cuff is immediately deflated by completely opening the valve.
 - iv. The peak inflation level is determined by adding 30 mm to the pressure where the radial pulse disappeared.
5. The venous blood pool in the forearm is normalized by waiting at least 30 seconds or by raising the arm for 5-6 seconds.
6. The brachial pulse is located and the bell of the stethoscope is placed immediately below the cuff at the point of maximal pulsation. If it is not possible to feel the brachial pulse, the bell of the stethoscope should be placed over the area of the upper arm immediately inside the bicep muscle tendon. The bell should not touch the cuff, rubber or clothing.
7. The cuff is rapidly inflated to the peak inflation level and then deflated at a rate of 2 mmHg per second.
8. The pressure should be reduced steadily at this rate until the occurrence of the systolic level at the first appearance of a clear repetitive tapping sound (Korotkoff Phase 1) and the diastolic level at the disappearance of the repetitive

sounds (Phase 5) have been observed. The cuff should then be rapidly deflated by fully opening the valve of the inflation bulb. Note: There may be a brief period (auscultatory gap) between systolic and diastolic pressure, when no Korotkoff sounds are heard. Thus the 2mmHg/second deflation should be continued until the diastolic blood pressure is definitely established. If Korotkoff sounds persist until the cuff is completely deflated, a diastolic blood pressure of 0 should be recorded.

9. The measurements should be recorded to the nearest 2 mmHg. If the top of the meniscus falls halfway between two markings, the marking immediately above is chosen. The subject is not told his/her blood pressure at this point.
10. After waiting one minute to allow for the redistribution of blood in the forearm, a second measurement is made by repeating steps 7 to 9. The subject should not change position during this wait.
11. After another minute, the third measurement is made by repeating steps 7 to 9.
12. The subject may now be told the measurements.

8.5.3 AUTOMATIC BLOOD PRESSURE MEASUREMENT

8.5.3.1 EQUIPMENT

For blood pressure measurements the following equipment is required:

- Automated blood pressure measurement device
- 3-4 cuffs
- Non-elastic measuring tape

8.5.3.2 MEASUREMENT PROTOCOL

1. Attach the air tube of the cuff to the air jack of the machine. The cuff must be airless.
2. Open the battery compartment and insert batteries or use the adapter.

3. Press the “On” button: all the symbols on the display will light up for approximately two seconds in order to check the display.
4. All of the symbols then disappear and the air release symbol begins to flash.
5. Wrap the cuff around the arm so that the coloured band (indicating the centre of the bladder) is positioned 2-3 cm above the elbow joint on the inside of the arm.
6. Close the cuff with the fabric fastener. The green area of the cuff must cover the brachial artery.
7. Push the start button: the device automatically determines the correct level of inflation pressure.
8. When the target inflation values are reached, the air is automatically released. The value in the display counts downwards.
9. As soon as the monitor detects the pulse, the symbol begins to flash.
10. When the monitor no longer detects the pulse while the cuff pressure is dropping, the systolic and diastolic pressure are displayed.
11. After one minute, the second measurement is made by repeating steps 7-10. The subject should not change position during this wait.
12. After another minute, the third measurement is made by repeating steps 7-10.
13. The subject may now be told the measurements.

8.5.4 RECORDING FORM

From blood pressure measurements, at least following information should be recorded:

Participant's identification code:	_ _ _ _ _ _ _
Measurer's identification code:	_ _ _
Date of the measurement (dd.mm.yyyy):	_ _ _ . _ _ _ _ _ _ _
Time of day (hh:mm):	_ _ _ : _ _
Room temperature (°C):	_ _

Type of measuring device:	<input type="checkbox"/> Mercury sphygmomanometer <input type="checkbox"/> Automated device. Specify brand type model: <hr/> <input type="checkbox"/> Other, specify: <hr/>	
Number of the measurement device:	<input type="text"/> <input type="text"/> <input type="text"/>	
Arm circumference (cm):	<input type="text"/> <input type="text"/> <input type="text"/>	
Used cuff (width) size:	<input type="checkbox"/> 8 cm <input type="checkbox"/> 12 cm <input type="checkbox"/> 16 cm	
Arm used for the measurement:	<input type="checkbox"/> Right <input type="checkbox"/> Left	
Reason for use of left arm:	<input type="checkbox"/> Amputation of right arm <input type="checkbox"/> Cast on right arm <input type="checkbox"/> Open wounds/ sores on right arm <input type="checkbox"/> Rash on right arm <input type="checkbox"/> Arterovenous shunt/ other intravenous access device on right arm <input type="checkbox"/> Other, specify: <hr/>	
Posture of the subject during the measurement:	<input type="checkbox"/> Sitting <input type="checkbox"/> Supine	
Reason for supine posture:	<input type="checkbox"/> Bed driven <input type="checkbox"/> Other, specify: <hr/>	
Pulse rate:	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	
Blood pressure measurements:	1 st measurement: Systolic: Diastolic: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> 2 nd measurement:	

	Systolic:	Diastolic:
	_ _ _	_ _ _
	3 rd measurement:	
	Systolic:	Diastolic:
	_ _ _	_ _ _

8.5.5 HIS QUESTIONS

The HIS questions are provided in the Annex 1.

8.5.6 SELECTION AND TRAINING OF THE MEASURERS

When recruiting the measurers, the following should be kept in mind:

- Trained nurses and paramedics are often better at measuring blood pressure than doctors.
- The workload of measurers should not cause fatigue, which leads to false measurements.

All candidates have to undergo thorough training, which should cover both the theory and practice of indirect blood pressure measurements. The theoretical training is same for all the devices, whereas practical training differs with the specific devices.

During the theoretical lectures, the blood pressure measurement protocol is reviewed and discussed in detail. Possible problems during field operation are examined and solutions are analyzed. The quality control measures during the survey are also discussed (e.g., monitoring for terminal digit preference).

The practical training includes performing measurements with real subjects.

Special features for mercury sphygmomanometer

After persons have been recruited as candidates for the blood pressure measurement by auscultation method, they have to pass a hearing test administered by an audiometrist, to ensure they have no loss of hearing in either ear.

The practical training includes:

- Training with an audio tape of recorded Korotkoff sounds;
- Training with actual subjects (Y-tube, repeated measurements).

Before being accepted as blood pressure measurers, the candidates have to pass a certification test that could be based on techniques that are similar to the training methods, requiring that the candidate obtain a certain percentage of correct measurements in order to be certified.

Special features for automated device

No special requirement for training.

8.5.7 QUALITY CONTROL

8.5.7.1 DURING THE SURVEY

Quality assurance procedures mainly do not depend on the specific device. There are some device-specific features which are given separately for the mercury sphygmomanometer and the automated blood pressure measurement device.

Every day, before the first measurement is taken, the measurer should ensure that the mercury column of the sphygmomanometer is at zero, that the mercury column falls smoothly when the cuff is deflated, and that the column latches properly in the vertical position; any equipment failing these tests has to be replaced. The results should be recorded in a log book.

Measurers' performance should be monitored continuously, so that any unreliability can be detected early and the discarding of a large amount of data can be avoided. Although every blood pressure measurement cannot be monitored on site, there are several simple indicators that can be calculated regularly for monitoring purposes. For monitoring to be effective, measurements from the field should be reviewed regularly, preferably daily.

For each measurer, the following information should be checked regularly during the survey:

1. Availability of data for selected cuff width, measured arm circumference, room temperature and time of day, to determine if a measurer is omitting some parts of the protocol.

2. The proportions of identical readings for the first and second measurements, the second and third measurements, and for all three measurements of systolic and diastolic measurements separately, to determine if a measurer is actually taking three measurements (identical readings should be rare).
3. Daily/hourly work load, to ensure that it does not exceed the established limits.
4. Cross-tabulation between used cuff width and measured arm circumference, to determine compliance with the protocol.
5. Difference between systolic and diastolic blood pressure.

If problems are detected, they need to be immediately discussed with the individual measurer, and corrective action must be taken. It may suffice to make the measurer aware that he/she has problems with the measurement procedures; otherwise, the measurer should be retrained and re-certified or dismissed.

During extended surveys, a refresher session for all blood measurers should be held every three months.

During the survey, the room temperature should be monitored on a regular basis and adjusted when needed.

An external auditor should make surprise visits to the examination sites and observe measurers' performance by documenting step-by-step compliance with the protocol. Auditors should also act as a guest subject and participate actively in all steps of measuring blood pressure.

Special features for the mercury sphygmomanometer

As mentioned, every day, before the first measurement is taken, the measurer should ensure that the mercury column of the sphygmomanometer is at zero, that the mercury column falls smoothly when the cuff is deflated, and that the column latches properly in the vertical position; any equipment failing these tests has to be replaced. The results should be recorded in a log book.

For each measurer, the distribution of terminal digits for systolic and diastolic measurements (separately) should be checked regularly, to determine if:

- I. some measurers tend to prefer some digits over others (for example, zero preference), indicating unreliable detection of Korotkoff sounds;

- II. some measurers use odd digits which, according to the protocol, should not be used.

For each measurer, the mean and standard deviation of the systolic and diastolic blood pressure measurements should be checked regularly, to determine if the measurer produces readings that are systematically lower or higher than the team average.

Special features for the automated device

The equipment should be calibrated by an official institute, both before the survey and at least once a year during the survey.

The batteries of the device should be checked every day before the first measurement is taken and several times during the day.

For each device, the mean and standard deviations of the systolic and diastolic blood pressure measurements should be checked regularly, to determine if a device produces systematically lower or higher readings than the average.

8.5.7.2 QUALITY ASSESSMENT AFTER THE SURVEY

After the survey, it is important to assess and document the overall quality of blood pressure measurements, to verify that the published results are accurate and comparable with those of other studies and to plan future surveys and develop future training.

The retrospective quality assessment report for blood pressure measurements no longer focuses on the data of individual measurers but instead concentrates on the pool of all measurements; the report should include the following information:

1. Item response rates for blood pressure measurement;
2. Availability of data on:
 - a. cuff width used
 - b. measured arm circumference
 - c. room temperature
 - d. time of day of the blood pressure measurement
3. Proportion of incomplete measurements;

4. Proportion of identical measurements for systolic and diastolic measurements separately;
5. Difference between two sequential measurements for systolic and diastolic measurements separately;
6. Cross-tabulation between cuff widths and arm circumferences; and
7. Mean and standard deviation of the room temperature.

If a mercury sphygmomanometers is used, the report should also include the following:

1. Proportion of odd-valued readings for systolic and diastolic measurements separately; and
2. Distributions of terminal digits for systolic and diastolic measurements separately.

8.6 BLOOD COLLECTION

Venous blood samples are usually collected to measure blood lipids and glucose. For lipid measurements, serum should be used; for glucose measurements, plasma is used. It is often advisable to collect additional serum and plasma samples for the possible future analysis of fatty acids and lipoproteins, biomarkers and antibodies, and whole blood for DNA. The collection of blood samples for the analysis of blood lipids and glucose are described here.

Minimal set of blood measurements: The minimal set of analyses contains the lipid analyses:

- Total Cholesterol
- High density lipoprotein (HDL) cholesterol

The set of analyses can be extended by taking (citrate + sodium fluoride) samples for measuring:

- Glucose

Age: Blood can be drawn from participants aged 4 years and older.

Exclusion criteria: Reason for exclusion of participants:

- Participant is undergoing anticoagulation therapy
- Participant has a bleeding disorder (e.g., haemophilia, low platelets, etc).

Time of measurement: Drawing blood samples will take about 15 minutes.

8.6.1 EQUIPMENT

Equipment for drawing a blood samples

- needles (preferably vacutainer needles), size 20G to 22G
- vacutainer tubes
- vacutainer holder
- tourniquet
- micropore tape
- adhesive dressing
- rubber gloves
- pillow or other support
- separate stoppers for open vacuum tubes and non-vacuum tubes
- needle disposal box

Chemically clean evacuated tubes with appropriately reduced pressure should be used in sample drawing. If plasma specimens are taken, EDTA should be used as anticoagulant. Tubes with liquid EDTA reduce the risk of haemolysis which sometimes occurs with tubes when using EDTA in powder form. For glucose determination, tubes with citrate and sodium fluoride are needed.

Plastic vacuum tubes are preferred to glass tubes. Plastic vacuum gel tubes are the most convenient, if available.

Plain tubes can be used for the determination of lipids (total cholesterol and HDL cholesterol).

If vacuum tubes are not used or tubes are opened for freely flowing samples, stoppers that do not react with blood constituents should be available.

Equipment for handling, transfer and storage

For handling, transfer and storage of blood samples the following equipment is needed:

- transfer and storage tubes (note that some of these should be freezable)
- disposable pipettes or pipettes with changeable apex
- centrifuge, capable of 3,000g. If gel tubes are used, the centrifuge should have a swinging bucket rotor
- timer
- racks for tubes
- special boxes for tube transfer and storage
- set of labels with identification codes or other method to mark the tubes (note that these should not be vulnerable to freezing)
- refrigerator
- freezer (as required)

8.6.2 PROTOCOL FOR DRAWING BLOOD SAMPLES

Fasting before the sample collection

The serum samples for total cholesterol and HDL cholesterol can be taken at any time of the day, with the subject non-fasting. If drawing non-fasting samples, the sample drawing should be spread out over the entire day.

If measuring fasting glucose, lipoprotein fractions and triglycerides, the samples should be collected after a fasting period of at least 8 hours and at most 14 hours (excessively long fasting causes major changes in energy metabolism, with implications for blood triglycerides) [4]. In practise, this means that fasting must be overnight and that the samples can only be taken in the morning and can only be expected from persons who are invited to undergo the examination in the morning.

Position of the subject

All blood samples should be drawn with the subject in a sitting position. Preferably, blood should not be collected from the arm that is used for blood pressure measurement, (i.e., blood should usually be drawn from the left arm).

Use of a tourniquet

Prolonged venous occlusion can cause changes in concentrations of blood constituents. Therefore, the use of a tourniquet should be minimized. If a tourniquet is used to search for a vein, it should be released before withdrawal of blood begins. In any case, the use of a tourniquet should be limited to less than one minute.

Sample drawing procedure

Blood samples should be taken from the vein in the antecubital fossa. Before blood collection, the subject should remove any tight clothing that could constrict the upper arm. During blood collection, the arm should rest on a pillow or other supportive prop.

The measurer sets the tourniquet around the subject's upper arm and searches for the proper vein by inspecting and palpating. The vein can be anchored by placing the thumb about two centimetres below the vein and pulling gently to make the skin a little taut. The needle, bevelled upward, should then be pushed smoothly and quickly into the vein, to minimize the possibility of haemolysis as a result of vascular damage. Immediately after the insertion, the tourniquet should be released to minimize the effect of hemoconcentration.

The order in which the various tubes are filled is determined by the risk of contamination and coagulation; the Clinical and Laboratory Standards Institute recommends the following order: 1. tubes for serum, 2. sodium citrate filled tubes, 3. gel tubes, 4. heparin filled tubes, 5. EDTA filled tubes, and 6. fluoride filled tubes. If there is an insufficient amount of blood and not all of the assays can be performed, the priority of the assay should also be taken into consideration in determining the order in which the tubes are filled, which would then be: 1. tubes for serum, and 2. tubes filled with fluoride.

If there are any problems with blood flow during blood taking (e.g., collapsing vein), the procedure should be discontinued and an attempt should be made on the other

arm. If this also fails, no further attempts should be made, and the blood collection for this particular participant should be recorded as "failed".

If vacuum tubes are used, the tube is placed in the adapter. When taking several tubes, the next tube should be changed immediately after the previous one is filled. If the measurer suspects that there will not be enough blood to fill all of the tubes, then they should be filled in the order of priority of the assay for which they are needed. To assure proper mixing, the tubes pre-filled with EDTA, gel or fluoride should be inverted smoothly about 8 times towards the stopper while the next tube is being filled (for the sake of simplicity, the manual of operations for this procedure could prescribe inverting all tubes, since it does not harm plain tubes).

Before the subject leaves the examination site and before the rack is moved anywhere, all of the tubes should be labelled with the subject's identification code.

Clotting

After the tubes are labelled with identification, the timer should be started. The blood samples are allowed to clot at 15-24 °C. If vacuum gel tubes are used, the temperature should be at least 20°C (optimum 20-22°C), given that the gel viscosity changes in colder temperatures. The clotting time should be at least 30 minutes and at most one hour.

Blood samples should be centrifuged within one hour of blood collection. Serum samples should be cooled in the refrigerator immediately after clotting and centrifuged at the end of the day.

The centrifuge should not be cold and blood specimens should be centrifuged at 15-24°C. For serum preparation, blood should spin for 10 minutes at 1,500 g. For plasma, the conditions are: 15 minutes at 2,000 - 3,000 g. For all subjects, a form should be filled out with information on the handling of the blood samples (see Chapter 8.6.3).

Separation of serum or plasma

After centrifugation, the tubes should be inspected carefully to recognize possible haemolysis. If vacuum gel tubes are used, it should be checked that the gel surface is straight, the layers are properly separated, there are no red cells above the gel surface, there are no fibrin filaments in the sample and the sample has not coagulated after centrifugation. If the serum samples are pooled, the haemolysed samples should be kept separate.

The serum/plasma should be promptly separated from clot or cells and transferred to a clean tube. The white-cell layer should not be transferred with the plasma. If vacuum gel tubes are used, the separated serum can be poured into a clean tube; otherwise a pipette should be used.

After all serum/plasma is separated into proper transfer/storage tubes, the tubes should be carefully marked with the identification code.

Storage and transfer of serum/plasma samples

It is recommended that the assays for total cholesterol, HDL cholesterol and triglyceride levels be done on the day of sample collection. For transport from the examination site to the laboratory, the samples should be properly packed and cooled, but not frozen.

If HDL cholesterol is analyzed with the precipitation method, the analysis should be done on the day of blood collection; however, it is currently recommended that HDL cholesterol be analyzed using a direct method.

If it is not possible to perform the analysis on the day of sample collection, yet possible within three days, it is recommended that non-frozen samples be used and that they be stored at +4°C before analysis.

If it is not possible to perform the analysis within three days, the serum or plasma should be immediately frozen (preferably at -70°C but at least at -20°C). While transporting frozen samples, care must be taken to avoid thawing.

For transport, the samples should be properly marked with the identification codes, and transfer lists should be kept, in order to check for the possible disappearance of samples.

Samples frozen at -20°C should be analyzed within six months. If later analyses are planned, the samples must be frozen at -70°C.

8.6.3 RECORDING FORM

From blood sample collection, at least following information should be recorded:

Participant's identification code:	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Identification code of person drawing the blood samples:	<input type="text"/> <input type="text"/> <input type="text"/>
Date of sample collection (dd.mm.yyyy):	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Time of day (hh:mm):	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Time of last meal (hh:mm):	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Posture of the subject during the blood collection:	<input type="checkbox"/> Sitting <input type="checkbox"/> Supine
Reason for supine posture:	<input type="checkbox"/> Fainted <input type="checkbox"/> Bed driven <input type="checkbox"/> Other, specify: _____
Arm used for blood collection (if blood collection, failed, code the arm where the last attempt was made):	<input type="checkbox"/> Left <input type="checkbox"/> Right
Reason for use of right arm:	<input type="checkbox"/> No vein found on left arm <input type="checkbox"/> Amputation of left arm <input type="checkbox"/> Cast of left arm <input type="checkbox"/> Other, specify: _____
Number of tubes collected:	<input type="checkbox"/> All <input type="checkbox"/> Only <input type="text"/> tubes <input type="checkbox"/> None
Reason for missing blood samples:	<input type="checkbox"/> Vein could not be found/ difficult to take a blood sample <input type="checkbox"/> Refusal <input type="checkbox"/> Other, specify: _____

From sample handling in the field, at least following information should be recorded:

Participant's identification code:	_ _ _ _ _ _ _
Identification code of person handling the blood samples:	_ _ _ _
Date of sample handling (dd.mm.yyyy):	_ _ _ _ _ _ _ _ _ _ _ _ _
Time of day for centrifuging (hh:mm):	_ _ _ _ _ _ _
Hemolyse sample:	_ Yes, all _ Yes, _ tubes _ No
<i>If samples are frozen already on the field:</i>	
Date when samples where frozen (dd.mm.yyyy):	_ _ _ _ _ _ _ _ _ _ _ _ _
<i>If samples are send to central laboratory:</i>	
Date when samples where send (dd.mm.yyyy):	_ _ _ _ _ _ _ _ _ _ _ _ _
Shipment number:	_ _ _ _ _ _ _

From final sample handling, at least following information should be recorded:

Participant's identification code:	_ _ _ _ _ _ _
Identification code of person handling the blood samples:	_ _ _ _
<i>If samples are send from field to central laboratory:</i>	
Date when samples where received from the field (dd.mm.yyyy)	_ _ _ _ _ _ _ _ _ _ _ _ _
<i>For all samples:</i>	
Date of sample handling (dd.mm.yyyy):	_ _ _ _ _ _ _ _ _ _ _ _ _
Number of serum tubes stored:	_

Number of plasma tubes stored:	__
Number of whole blood tubes stored:	__

8.6.4 SAFETY

Medical doctor for back-up

During the examinations, the nurse/medical assistant who takes the blood samples should know who they can contact (i.e., a medical doctor) in case something happens with the participant during or after the blood drawing.

Gloves

For safety reasons, gloves should be used during blood drawing and handling. Whether or not gloves are used may depend on local instructions/protocols. If the personnel drawing blood samples do not use gloves, they should wash their hands between each participant.

Vaccination for hepatitis B for medical personnel

All medical personnel working with needles should be vaccinated for hepatitis B. The head of the department or project leader is responsible for ensuring that the staff is immunised.

Needle stick injuries

The protocol for needle-stick injuries should be posted at the examination site. Anyone who sustains a needle-stick injury should seek immediate assistance from the local health staff responsible.

What to do if a needle-stick injury occurs?

- Let the wound bleed very well and clean it with water or physiological saline.
- Disinfect the wound.

- Contact the local health professional who is responsible for infectious diseases.

Disposal of needles and other materials

Needle disposal boxes should be available. The needles should be released from the adapter directly into the needle disposal box. The needle should never be re-sheathed after use. The disposal box should not be allowed to become overfull (filled to a maximum of 75%). All of the remaining materials (needles / rest blood) should be processed in an appropriate way, and in accordance with any local regulations.

8.6.5 QUALIFICATION AND TRAINING OF PERSONNEL

The person performing the blood collection should be a certified phlebotomist. In most countries, this certification is offered through national accrediting agencies for clinical laboratory sciences. Employing a certified phlebotomist for the invasive blood collection procedure provides not only a measure of safety for the participant but also some medical-legal protection for the survey organizers, in case something should go wrong.

In preparing for the survey, the personnel responsible for collecting blood should be familiarised with the aims of the survey and with that part of the protocol that pertains to blood collection. The safety measures for protecting the participant and the technician should be reviewed.

8.6.6 HIS QUESTIONS

The HIS questions for the HES can be found in Annex 1.

8.6.7 QUALITY CONTROL

Equipment

Check the expiration date of the vacutainers.

Procedures

Surprise visits should be made to the examination sites to observe field personnel and verify compliance with the protocol. A previously agreed upon check list should

form the basis for these observations. Blood samples should be traceable to the individual phlebotomist. The compliance of the phlebotomist with the exclusion criteria for blood collection should be checked by cross validation with questionnaire data. Phlebotomists may also be assessed by determining the number of failed blood collection procedures.

8.7 LABORATORY PROCEDURES

8.7.1 LABORATORIES

All laboratory procedures should be carried out only in accredited medical chemistry laboratories.

8.7.2 ANALYTICAL PROCEDURES

Good direct enzymatic methods are available for performing assays for total, LDL and HDL cholesterol, as well as for glucose. These can be used with automated or manual methods with inexpensive instruments. The U.S. Centres for Disease Control and Prevention (CDC) has a certification program for clinical diagnostic products for cholesterol [5].

8.7.3 QUALITY CONTROL

Internal quality control of laboratory analyses

For each type of assay, the laboratory has to obtain quality control material. Particularly important is the secondary calibrator, which should be real human serum or plasma in the same form as the survey blood samples. These secondary calibrators should be traceable to an internationally recognized reference method. Each standard (calibrator) should be run at least in duplicate. The linearity over the usual working range of the assay should be tested and checked repeatedly during the study. The linearity should be checked with at least three standards in each run.

External quality control of laboratory analyses

External quality control is arranged by internationally recognized reference laboratories which distribute batches of samples of various concentrations for each assay. The participating laboratory is blinded to the concentration of the analyte. Bias

and standard deviations of the results of the participating laboratory serve as a measure of performance. Laboratories should participate in the external quality control scheme for the duration of the study. (No such external quality control is currently available for the European HESs, but a recommendation for its establishment is made in Chapter 11.)

8.8 PHYSICAL FUNCTIONING

8.8.1 UPPER BODY FUNCTIONING

8.8.1.1 HANDGRIP STRENGTH

Handgrip strength is often used as an indicator of overall muscle strength in population studies. It has also been shown to be a powerful predictor of mortality. A wide range of instruments and measurement protocols are available to measure handgrip strength. Hydraulic instruments (dynamometers) are the most widely used and recommended instruments.

Aim of the test: The handgrip measurement is to determine the strength of the dominant hand (i.e., the writing hand). This should be asked before the measurement. If the participant is unable to use the dominant hand, the test should be performed on the non-dominant hand. This information and the reason for which the dominant hand cannot be used should be reported.

Age: It is recommended that handgrip strength be measured from all persons aged 30 years and older [6].

Exclusion criteria: People with swelling or inflammation, severe pain or injury (e.g., fracture), and those who have undergone surgery to the hand in the previous 6 months should not take the test. Bad arthritis and rheumatology may also prohibit the measurement, as may dementia and some other cognitive problems (e.g., if the participant does not understand the instructions). The reasons for not conducting the test should be reported.

Time of measurement: The measurement of handgrip strength requires approximately 3 to 5 minutes.

8.8.1.1.1 Equipment

Standard handheld dynamometer (hydraulic instruments).

8.8.1.1.2 Measurement protocol

Testing position

A standard position for testing adapted from the recommendation of the American Society of Hand Therapists is recommended. The participant should assume the following position:

- Seated in a straight-backed chair
- Feet flat on the floor
- Shoulders adducted in neutral
- Arms unsupported
- Elbow flexed at 90 degrees (from the dominant hand)
- Forearm rotation neutral
- Wrist 0-30 degrees dorsiflexion and 0-15 degrees ulna deviated
- The arm that is not measured can be placed on the side of the body or on the lap.

The dynamometer should be placed in the hand so that the wrist is in neutral position (slight dorsal flexion). The grasp is somewhat the same as that used when giving a handshake. Variations of this position significantly influence the results.

Adjustment of the device

Dynamometers are usually variable handspan instruments with different positions for measurements (usually 5 different positions). The device should be adjusted to fit the size of the participant's hand so that the second joint of the forefinger is in 90 degree flexion. If the device is too small, the hand will make a fist. Before starting the measurement, the participant should be asked whether the grasp feels as if it is the natural size.

Instructions

Illustrate the use of the instrument to the participant prior to testing. When the correct testing position is found, the test can be started.

The participant is asked to squeeze the dynamometer with as much force as possible, being careful to squeeze only once for each measurement. Be sure that the body is not used in the measurement (e.g., the trunk must be in place). The tester needs to encourage the participant to do his/her best during the measurement, saying to the participant: *“The test is beginning...Now! Squeeze! Squeeze! Squeeze! Good, you can stop now and rest”*.

Each squeeze should last from 3 to 5 seconds. The way in which the participant is encouraged affects the results and should thus be the same for all participants. Three trials should be made with a pause of about 10-20 seconds between each trial, to avoid the effects of muscle fatigue.

The result of each trial should be recorded to the nearest pound or kilogram. If the difference in scores is within 3 kg, the test is complete. If the difference between any two measures is more than 3 kg, the test should be repeated once more after a rest period. The best 3 measurements (i.e., the highest three) should be recorded. When a 4th measurement is taken (when any of the 3 measurements are 3 kg apart) be sure the outlier (the LOWEST value) is crossed off with your initials so that the 3 HIGHEST values are clearly indicated for data entry.

8.8.1.1.3 Recording form

From handgrip strength, at least following information should be recorded:

Participant's identification code:	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Measurer's identification code:	<input type="text"/> <input type="text"/> <input type="text"/>
Date of measurement (dd.mm.yyyy):	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Dominant hand:	<input type="checkbox"/> Right <input type="checkbox"/> Left
Reason why dominant hand was not used:	<input type="checkbox"/> Swelling or inflammation <input type="checkbox"/> Severe pain or injury <input type="checkbox"/> Surgery to the hand in the last 6 months

Measurement results:	1 st measurement: _ _ kg 2 nd measurement: _ _ 3 rd measurement: _ _ 4 th measurement: _ _
Reason why the measurement was not done:	<input type="checkbox"/> Swelling or inflammation on both hands <input type="checkbox"/> Severe pain or injury in both hands <input type="checkbox"/> Surgery to both hands in last 6 months <input type="checkbox"/> Arthritis or rheumatology

8.8.2 LOWER EXTREMITY

8.8.2.1 WALKING SPEED TEST

Walking speed has been shown to be a good predictor of nursing home admission, morbidity and mortality. It has also been shown to be a good predictor of disability outcome. Gait speed is a measurement based on a simple performance and is easily and quickly assessed in clinical and research settings.

Aim of the test: Walking speed test is to measure the normal walking speed over a 4-meter distance [7, 8]. The starting- and finish-lines of the distance are marked on the floor with tape.

Age: It is recommended that walking speed be measured for all persons aged 50 years and older.

Exclusion criteria: Walking speed is not measured for wheelchair bound individuals or people with severe difficulties in walking or maintaining a standing position. Walking aids (canes, walkers, etc.) that are used for normal walking in daily

activities are allowed. However, if these are used when performing the test, this needs to be recorded. Dementia and some other cognitive problems may also prohibit the measurement (e.g., if the participant does not understand the instructions). The reasons for not conducting the test should be reported.

Time of measurement: The measurement of walking speed will take approximately 1 minute.

8.8.2.1.1 Equipment

A stopwatch is needed to measure the time it takes to walk the distance and tape is needed to mark the starting- and finish-lines of the test (e.g., mark on the ground the distance that should be walked: 4 meters [9]).

8.8.2.1.2 Measurement protocol

The participant should be asked to walk the 4-meter distance at normal walking speed. The time will be recorded to the nearest 0.1 second. The test will begin to be timed when the tester says “Now” and ended when the trunk of the participant crosses the finish-line.

If the participant is able to walk normally and the risk of falling or banging into something is minimal, the tester can stand at the finish-line. If the participant’s walk is unsure or insecure, the tester should walk by the side of participant.

When a walking stick or other devices are used during the test, this should be recorded (See textbox 8.7).

Instructions

Instruct the participant to ‘*Walk to other end of the course at your usual speed, just if you were walking down the street to go to the store. You should start from here (show the line) and walk over the finishing-line of the test. I will take the time it takes to walk. Are you ready?....Go*’

8.8.2.1.3 Recording form

From walking speed test, at least following information should be recorded:

Participant's identification code:	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Measurer's identification code:	<input type="text"/> <input type="text"/> <input type="text"/>
Date of the measurement (dd.mm.yyyy):	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Measurement result (sec):	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Was any walking aid been used?	<input type="checkbox"/> None <input type="checkbox"/> Cain <input type="checkbox"/> Crutches <input type="checkbox"/> Walker <input type="checkbox"/> Other, specify: _____
Reason why the measurement was not done:	<input type="checkbox"/> Time exceeded 1 minute limit <input type="checkbox"/> Person could not walk <input type="checkbox"/> Security reasons (walking too unstable) <input type="checkbox"/> Other, specify: _____

8.8.2.2 TEST OF STANDING BALANCE

Balance and co-ordination are needed to successfully perform everyday loco-motor functions at reasonable speeds and to prevent falls.

Aim of the test: The test is to measure standing balance in three different positions, including semi-tandem, side-by-side and full-tandem stands.

Age: It is recommended that standing balance be measured for persons aged 60 years and older [10].

Exclusion criteria: Standing balance is not measured for wheelchair bound individuals or people with severe difficulties in maintaining a standing position (e.g., persons with a leg fracture). Dementia and some other cognitive problems may also prohibit the measurement (e.g., if the participant does not understand the instructions). The reasons for not conducting the test should be recorded.

Time of measurement: The measurement of semi-tandem and side-by-side and full-tandem stand will take approximately 5 minutes.

8.8.2.2.1 *Equipment*

A stopwatch is needed to measure the time of standing in a certain positions.

8.8.2.2.2 *Measurement protocol*

The standing balance test includes semi-tandem and side-by side or tandem stands. For each stand, the tester must first demonstrate the task; he/she must then support the participant by one arm while the participant positions his/her feet. The tester then asks if the participant is ready to start the test; the tester then releases the participant's arm and starts timing. The timing will be stopped when the participant moves his/her feet or grasps the tester for support, or when 10 seconds has elapsed.

Each participant starts the test from a semi-tandem stand, with the heel of one foot placed to the side of the first toe of the other foot. The participant can choose which foot to place forward. Those unable to hold the semi-tandem position for 10 seconds will be evaluated with feet in a side-by-side position. Those able to maintain the semi-tandem position for 10 seconds will be further evaluated with feet in full tandem position, with the heel of one foot directly in front of the toes of the other foot (see Figure 8.1).

Figure 8.1. Standing balance positions

1) Semi-tandem



2a) Side-by-side



2b) Tandem



Instructions

1) Semi-tandem

Explain and demonstrate the semi-tandem stand to the participant. Stand to the side of the participant and support one arm while the participant positions his/her feet. Ask if the participant is ready to start the test and then release the support and start timing. Press the start button to start the stopwatch as soon as the respondent gets into the position and is free of support. Stop the stopwatch and say “*Stop*” after 10 seconds or

when the participant steps out of position or grabs your arm. Record the result as “succeeded / un-succeeded”.

2a) Side-by-side

Participants unable to hold the semi-tandem position for 10 seconds will be evaluated with feet in a side-by-side position. Explain and then demonstrate the side-by-side stand to the participant. Stand to the side of the participant and support one arm while the participant positions his/her feet, if needed. Ask if the participant is ready to start the test and then release the support and start timing. Press the start button to start the stopwatch as soon as the participant gets into the position and is free of support. Stop the stopwatch and say “*Stop*” after 10 seconds or when the participant steps out of position or grabs your arm. Record whether or not the participant was successful.

2b) Tandem

Participants able to maintain the semi-tandem position for 10 seconds will be further evaluated with feet in full tandem position, with the heel of one foot directly in front of the toes of the other foot. Explain and then demonstrate the full tandem stand to the participant. Stand to the side of the participant and support one arm while the participant positions his/her feet. Ask if the participant is ready to start the test and then release the support and start timing. Press the start button to start the stopwatch as soon as the respondent gets into the position and is free of support. Stop the stopwatch and say “*Stop*” after 10 seconds or when the participant steps out of position or grabs your arm. Record the result as “succeeded / un-succeeded”.

In each position, if the participant is not capable of doing this test, do not attempt the movement. If the participant is unable to hold the position for 10 seconds, record the time in seconds. If the respondent did not attempt the measure, record the reason.

8.8.2.2.3 Recording form

From standing balance test, at least following information should be recorded:

Participant’s identification code:	_ _ _ _ _ _ _
Measurer’s identification code:	_ _ _
Date of the measurement (dd.mm.yyyy):	_ _ _ . _ _ _ . _ _ _ _ _

Semi-tandem stand:	<input type="checkbox"/> Succeeded
	<input type="checkbox"/> Un-succeeded
Side-by-side stand:	<input type="checkbox"/> Succeeded
	<input type="checkbox"/> Un-succeeded
Tandem stand:	<input type="checkbox"/> Succeeded
	<input type="checkbox"/> Un-succeeded
Reason why the measurement was not done:	<input type="checkbox"/> Wheelchair bound
	<input type="checkbox"/> Difficult to stand
	<input type="checkbox"/> Bed driven
	<input type="checkbox"/> Other, specify: _____

8.8.2.3 UNASSISTED SINGLE-LEG STAND

Aim of the test: The test measures the standing balance and multiple domains of functioning [11].

Age: It is recommended that unassisted single-leg-stand be conduct for all participants aged 30 years and older.

Exclusion criteria: Single-leg stand is not performed for wheelchair bound individuals or people who have severe difficulty with keeping a standing position (e.g, persons with a leg fracture). Dementia and some other cognitive problems may prohibit the measurement (e.g., if the participant does not understand the instructions). The reasons for not conducting the test should be reported.

Time of measurement: The total measurement will take about 3 minutes.

8.8.2.3.1 Equipment

Stopwatch

8.8.2.3.2 Measurement protocol

The leg raises should be performed next to a stable surface (e.g., a table or wall near) and the nurse should be positioned on the other side of the participant. The participant is expected to keep the single-leg standing position for 30 seconds. The

participant should take their foot off the floor and may hold it in any position which does not involve hooking around or touching the other leg for support.

Explain and then demonstrate the single-leg stand to the participant. Stand to the side of the participant and, if needed, support one arm while the participant positions his/her feet; ask if the participant is ready to start the test, release the support and start timing.

Instructions

“Now I will show you the NEXT movement. I want you to try to stand on one leg, whichever one you want, and raise the other leg off the ground a few inches (e.g., next to your ankle). Stand for as long as you can until I say ‘Stop’ – I will stop you at 30 seconds. You may use your arms, bend your knees or move your body to maintain your balance, but try not to move your feet. Try to hold the position until I tell you to stop. Do you feel that you could do this safely?”

If the participant says “no”, do not conduct the test. If the participant says it is safe, ask him/her to stand up. Stand to the side of the participant and say: “Ready, begin”. Press the start button to start the stopwatch as soon as the participant raises one foot off the ground and is free of support. Stop the stopwatch and say “Stop” when the raised leg touches the floor as the participant loses his/her balance or after 30 seconds, whichever happens first. Record the outcome on the collection form. If the participant is unable to hold the position for 30 seconds, record the time they held the position for.

8.8.2.3.3 Recording form

From unassisted single-leg stand, at least following information should be recorded:

Participant’s identification code:	_ _ _ _ _ _ _
Measurer’s identification code:	_ _ _
Date of the measurement (dd.mm.yyyy):	_ _ _ . _ _ _ . _ _ _ _ _
Single-leg stand:	_ Succeeded, full 30 seconds _ Succeeded, _ _ seconds _ Unsuccessful

Reason why the measurement was not done:	<input type="checkbox"/> Wheelchair bound <input type="checkbox"/> Difficult to stand (unsafe to conduct the measurement) <input type="checkbox"/> Bed driven <input type="checkbox"/> Other, specify: <hr/>
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8.8.2.4 TIMED CHAIR STAND TEST

Aim of the test: The test measures the ability to rise from a chair. It is a test of lower extremity and central strength, although other functional domains are also involved, such as endurance. The test involves measuring the time required to stand up from a chair and sit down in a chair 5 and 10 times without using one's arms.

Age: The timed chair stand test can be conducted for all persons aged 30 years and older.

Exclusion criteria: The timed chair stand test is not performed for wheelchair bound individuals or people who have severe difficulty with maintaining a standing position or walking and for those unable to stand up without help (e.g, persons with a leg fracture). Dementia and some other cognitive problems may also prohibit the measurement (e.g., if the participant does not understand the instructions). The reasons for not conducting the test should be reported. The use of walking aids is not permitted in this test.

Time of measurement: The total measurement will take approximately 2 to 3 minutes.

8.8.2.4.1 Equipment

A stopwatch and a standard high armless straight-backed chair (height 45 cm) are needed. If an ideal chair is not available, the following criteria for chair selection should be used in the order given:

- a) Armless, rather than with arms
- b) Firm (the firmer the better)
- c) Do not use beds, cots, folding chairs, garden chairs, chairs with wheels or chairs that swivel.

8.8.2.4.2 *Measurement protocol*

The chair should be placed next to the wall. The participant's feet should touch the floor when they are sitting (e.g., the chair should not be too high). Participants are asked to fold their arms across their chest and to stand up from the chair one time. If successful, participants will be asked to stand up and sit down five to ten times as quickly as possible. The timing will be started from the sitting position and end at the final standing position at the end of the fifth and tenth stands. The measurer should stand next to the participant, to be able to provide assistance if the participant loses his/her balance.

If the participant does not completed the single chair rise without using his/her arms, he/she is not eligible for the repeated chair rises; this and the reason for not completing the test should be recorded.

Instructions

Single chair stand

Explain and demonstrate the single chair stand to the participant. If the participant cannot rise without using his/her arms, say "Try to stand up using your arms". Record the outcome of the single chair stand. If the participant refuses to try the single chair stand or is unable to stand on his/her own without using the arms, do not attempt the repeated chair stand.

Repeated chair stand

Ask the participant to resume the sitting position that he/she was in just before standing up, with their feet resting on the floor and their arms folded across the chest. Explain the repeated chair stand. When the participant is properly seated, say "Ready, begin". Start the stopwatch as soon as you say "Ready, begin". Count out loud as the participant rises each time, up to 10 times. A rise is complete when the respondent is fully standing with their back straight. PLEASE NOTE: When the participant completes the fifth rise, press the split timer on the stopwatch. Continue counting out loud. When the respondent has straightened up completely for the tenth time, stop the stopwatch"

Stop if the participant becomes too tired or short of breath during the repeated chair stands. Also stop:

- If the participant uses his/her arms
- After 1 minute, if the participant has not completed all of the rises
- At your discretion, if you are concerned for the participant's safety

If the participant stops and appears to be fatigued before completing the ten stands, ask “*Can you continue?*”. If the participant says “Yes,” continue timing until 60 seconds has elapsed. If he/she says “No”, stop the stopwatch and record the number of completed stands without using arms. Be careful to enter the time for completing the first five stands first, before retrieving the time for the 10 stands from the stopwatch's memory.

8.8.2.4.3 *Recording form*

From timed chair stand, at least following information should be recorded:

Participant's identification code:	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Measurer's identification code:	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Date of the measurement (dd.mm.yyyy):	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
One chair stand:	<input type="text"/> Succeeded <input type="text"/> Unsucceeded
Time of the 5 chair stands:	<input type="text"/> <input type="text"/> <input type="text"/> sec only <input type="text"/> stands completed
Time of the 10 chair stands:	<input type="text"/> <input type="text"/> <input type="text"/> sec only <input type="text"/> stands completed
Reason why the measurement was not done:	<input type="text"/> Wheelchair bound <input type="text"/> Difficult to stand (unsafe to conduct the measurement) <input type="text"/> Bed driven <input type="text"/> Other, specify: _____

8.9 ANKLE BRACHIAL INDEX

Age: The ankle brachial index (ABI) can be determined for participants aged 40 years and older

Time measurement: The measurement will take about 5-10 minutes.

8.9.1 EQUIPMENT

Dobbler device, blood pressure cuffs, sphygmomanometer

8.9.2 MEASUREMENT PROTOCOL

There is no standardized protocol for measuring the ankle brachial index. Since it was introduced, a wide variety of methods have been used in studies. Klein et al. performed an analysis of all of the methods used and the normal range, so as to recommend a standardized method for assessing ABI [12].

Position of the participant

The supine position seems to be the position of choice because only in this position can the influence of the subject's height and blood column pressure be prevented.

Cuff

Ideally, the cuff width should be at least 1.5 times the diameter of that part of the extremity where the pressure is being measured, and the size of the cuff should be adjusted in obese patients or in patients with odd shaped arms or ankles.

Method of detection of the pulse in arm and leg

A pencil-Doppler should be used to detect the brachial pulse, given that this is the method that has been used in half of the reviewed studies. The measurements taken with this device were proven to correlate with the systolic pressure obtained using conventional methods, at high, medium, and low blood pressures.

Choice of arm and leg for measurement

The blood pressure should be taken at both arms and legs to rule out serious differences. From legs both dorsal pedal/ anterior tibial artery (DP/AT) and posterior tibial artery (PT) pressure should be measured.

Protocol (concept)

1. Systolic blood pressures are obtained using cuffs, a Doppler, and a cuff inflation device (sphygmomanometer).
2. Apply cuffs to each arm above the elbow.
3. Apply cuffs to each ankle.
4. Locate an arterial signal in the arm by listening with the Doppler at the brachial, radial or ulnar area.
5. Inflate the cuff to a pressure of 20-30 mmHg above the audible arterial Doppler signal.
6. Slowly deflate the cuff and listen for the return of blood flow to the distal part of the limb. Note the pressure reading when the first arterial signal is heard. This is considered the systolic pressure at the level of the cuff. Record this on the form.
7. Both arm systolic pressures are taken to determine the systemic blood pressure. The higher of the two pressures will be used in the calculation of the ratios
8. For ankle measurements follow the procedure as described in steps 4 through 6 above. Monitor either the dorsalis pedis or the posterior tibial artery, whichever gives the strongest signal. Record this on the form. Then monitor the posterior artery. Record this on the form.
9. If resting pressure measurements need to be repeated, the cuff should be fully deflated for about one minute prior to each inflation, so as to prevent the effects of induced reactive hyperemia.

Interpretation

The ankle brachial index is calculated separately for both legs by the dividing means of DP/AT and PT with the left brachial artery pressure.

8.9.3 RECORDING FORM

From arm brachial index, at least following information should be recorded:

Participant's identification code:	_ _ _ _ _ _ _
Measurer's identification code:	_ _ _
Date of the measurement (dd.mm.yyyy):	_ _ _ . _ _ _ . _ _ _ _ _
Left arm pressure	_ _ _
Right arm pressure	_ _ _
Left leg pressure	DP/AT _ _ _ PT _ _ _
Right leg pressure	DP/AT _ _ _ PT _ _ _
Reason why the measurement was not done	<input type="checkbox"/> Left arm amputated <input type="checkbox"/> Right arm amputated <input type="checkbox"/> Left leg amputated <input type="checkbox"/> Right arm amputated <input type="checkbox"/> Open wounds or other restrictions on left arm <input type="checkbox"/> Open wounds or other restrictions on right arm <input type="checkbox"/> Open wounds or other restrictions on left leg <input type="checkbox"/> Open wounds or other restrictions on right arm <input type="checkbox"/> Other, specify: _____

8.10 QUALITY ASSURANCE

For the quality assurance for the measurement protocols the recommendations are similar to those of the EHRM [2].

8.10.1 TRAINING

All fieldworkers will receive training before the actual work in the field. Training will include an instruction session, in which protocols are reviewed and discussed and measurements are practised. Possible difficult situations that might arise in the field are presented, and solutions are discussed. The quality control procedures to be performed during and after the survey will also be presented.

8.10.2 QUALITY CONTROL

Quality control measures during the survey involve checking and re-calibrating of equipment and monitoring of the performance of the measurers.

If problems are detected, they need to be discussed with the individual measurer immediately. Feedback to the measurers about the quality of their performance can help to improve the quality of the field work. If errors persist, the measurer should be retrained.

During extended surveys, sessions to refresh the quality aspects for all measurers every three months is a desirable practice.

Auditors should make surprise visits to the examination sites and observe the measurers, recording the compliance with the protocol in performance evaluation forms that can later be used to review the audit with the measurers. The auditors could also act as guest participants and take part in a number of measurements.

Blood samples should be traceable to the individual measurer. The compliance of the phlebotomist with the exclusion criteria for blood collection should be checked by cross validation with questionnaire data. Phlebotomists may also be assessed by the number of failed blood collection procedures.

8.10.3 QUALITY ASSESSMENT AFTER THE SURVEY

It is important to check the overall quality of the measurement. The quality assessment should include the item response rates for each measurement.

The data should be checked as soon as possible after the data collection for:

- outlandish values, i.e. for values which have not been defined, and also for values which are possible but rare (e.g. BMI of 40 kg/m²);

- consistency between the values of different data items e.g. the difference between systolic and diastolic blood pressure);
- completeness, i.e. that all data items have been recorded and no records have been missed.

Each error and its possible correction should be documented. The frequency of errors, which were not possible to solve should be documented. In addition, the results of the quality control during the data collection, any deviations from the survey protocol, and any other information which may be relevant in the interpretation of the results should be documented too. Knowledge of these issues is essential to those who analyze the data and interpret the results.

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9 DATA MANAGEMENT AND DOCUMENTATION

Hanna Tolonen¹, Kari Kuulasmaa¹

¹ National Public Health Institute, Helsinki, Finland

Two corner stones of the good health examination surveys are data management and documentation, which are closely linked to each other and in some places overlap. On the other hand, documentation and reporting are also linked to each other. Reporting is an important part of the utilization of the health examination survey results.

9.1 DATA MANAGEMENT

A well-organized data management is essential part of the health examination survey. It ensures that the available data are complete, correct and verifiable, and that the data analyses are done using correct data, without errors, and that the confidentiality of the data is secure. (Adopted from the [1])

Stages of the data management

- Planning;
- Sample selection and recruitment;
- Survey measurements;
- Data transfer and keying;
- Error checking, data correction, data documentation, database structure and documentation;
- Backup;
- Confidentiality;
- Correctness of data analysis;
- Analysis documentation;

9.2 DOCUMENTATION

With the proper documentation, the representativeness of the results to the target population, used procedures, data quality and the accuracy of the results is easier to identify and verify. (Adopted from [2])

The survey documentation should cover the entire survey process from the planning to the final report, i.e.:

- the objectives and rational of the survey,
- the definition of the target population and the eligibility within the target population,
- the description of the used sampling frame and how the actual sample was drawn,
- the determination of the sample size,
- the original references to the survey instruments which are adopted from other surveys or national/international recommendations,
- the description and validation of new survey instruments developed specifically for the survey,
- the requirements and selection of the survey personnel,
- the training program and results of the evaluation of the personnel,
- the actual implementation process of the survey,
- the quality control process carried out during the survey and their results,
- the methods used for data collection, transfer, coding and editing,
- the database structure,
- the data analysis:
 - which data set was used
 - what software and which version was used
 - where are the actual software codes used for the analysis

- the reporting of the results:
 - what has been reported
 - where it has been published
 - where are the analysis to which these results are based on.

Documentation is a collection of minutes of the meetings, specially prepared documents, original material (questionnaires, etc.), training materials, communication logs between coordinating office and fieldwork teams, data analysis documents including information about the used data sets, used computer programs (software and code), etc.

The documentation should be organized so that it is easily accessible to all who needed it.

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10 RESOURCES NEEDED AND PREPARATION OF A SURVEY BUDGET

Hanna Tolonen¹, Arpo Aromaa¹

¹ National Public Health Institute, Helsinki, Finland

10.1 ISSUES AFFECTING THE RESOURCES NEEDED

Conducting a national health examination survey (HES) requires resources, which include personnel costs and materials as well as possible travel expenses, accommodation, rent, transport of materials, etc. The type and amount of resources needed is dependent on the survey mode and survey size, i.e. what is measured, in what settings and from how many persons each has a direct effect on the resources required.

The budget gives the actual price tag for the resources needed and in many cases also gives the direction for the survey mode and size. The preparation of the budget should be started in the early stages of the planning. The extent of the survey i.e. number of measurements included and number of persons examined effects directly the resources required and the budget. The survey model, i.e. whether the survey measurements are conducted at the home of the participants, at the fixed examination clinics or on the mobile examination units, also has an effect on the resources required.

10.2 RESOURCES NEEDED FOR THE DIFFERENT STAGES OF HES

Conducting a health examination survey can be divided into 11 stages: (1) planning, (2) coordination, (3) training, (4) piloting, (5) sampling, (6) recruitment, (7) field work, (8) laboratory analysis, (9) data entry and cleaning, (10) quality assurance, and (11) analysis and reporting. Following lists what kind of personnel, equipment and other resources are most often needed in different stages.

10.2.1 PLANNING

The planning of the survey sets the foundation to the actual survey and therefore enough resources should be reserved for this task. The planning stage mainly requires personnel resources: senior researchers, advisers, data management, statisticians, and laboratory technicians who have special knowledge how different issues should be taken into account in the actual survey.

10.2.2 COORDINATION

Personnel requirements: Responsible person (usually senior researcher), coordinator and possibly secretary.

Equipment requirements: Computers (usually with internet connection), telephones / mobile phones, software licenses, and office materials (pens, papers, etc.).

Other needed resources: Premises for the coordinating office, travel and accommodation of the coordinator(s) to the field, and resources needed for the recruitment of the fieldwork personnel (newspaper adds, etc.).

10.2.3 TRAINING

Personnel requirements: Trainers, whose number and qualifications depend on survey contents.

Equipment requirements: Depends on measurements included. See list of equipments needed per measurement in Chapter 8.

Other needed resources: Travel and accommodation of the trainers, travel and accommodation of the trainees, and premises for the training.

10.2.4 PILOTING

Personnel requirements: Fieldwork personnel (number dependent on survey mode, and extend), data management person(s), statistician(s)s, and laboratory personnel.

Equipment requirements: Equipment obtained already for the training can be used in the pilot. There may be need to obtain extra for the pilot. Equipment needed for data transfer, and computers.

Other needed resources: Premises for the pilot, transport of the materials to and from the pilot site, and travel and accommodation of the personnel during the pilot.

10.2.5 SAMPLING

Personnel requirements: Statistician(s) for determination of sample size, selection and/or preparation of sampling frame, sample selection (may also be bought service from sampling frame owner), and data manager (computer resources, database manager).

Equipment requirements: Computers, and software licenses (database, etc.).

10.2.6 RECRUITMENT OF PARTICIPANTS

Personnel requirements: Person(s) preparing the invitation letters, questionnaires, other printed materials, person(s) doing recruitment (mailing of invitations, calling the appointments, answering request by phone and mail, etc.), and data manager.

Equipment requirements: Computers, telephones / mobile phones, and software licenses.

Other resources needed: Printing of the materials, mailing costs, telephone costs, home visit costs, reminder costs, toll-free telephone number for more information and examination time booking, incentives, and newspaper advertisement, radio advertisement, etc.

10.2.7 FIELDWORK

Personnel requirements: Fieldwork teams (number and qualification of the personnel depends on survey mode and extend), and data manager.

Equipment requirements: Equipment obtained already for the training and pilot can be used in the fieldwork. There may be need to obtain extras for the fieldwork. Office materials (pens, papers, etc.).

Other resources needed: Transport of the materials to the field examination site, transport for personnel to the field examination site, accommodation of the personnel during the field work period, storage of the materials in the field, transfer of the materials from field examination site to the coordination centre/laboratory, rents for the examination sites, and data transfer connections / phones / faxes etc.

10.2.8 LABORATORY ANALYSIS

Personnel requirements: Number and qualifications of the laboratory personnel depends on laboratory analysis needed and about the number of samples to be analyzed. Data management is also needed.

Equipment requirements: Allocation tubes, storage tubes, pipettes, storage tracks, storage boxes, and reagents.

10.2.9 DATA ENTRY AND CLEANING

Personnel requirements: Data entry person(s), statistician, and data management personnel.

Equipment requirements: Computers, software licenses, and scanners (if data is not keyed in manually but scanned).

Other resources needed: Transfer of the materials (questionnaires) to and from the data entry.

10.2.10 QUALITY ASSURANCE

Personnel requirements: Data manager, statistician and senior researcher/epidemiologist.

- *Equipment requirements:* Computers, and software licenses.

10.2.11 ANALYSIS AND REPORTING

Personnel requirements: Statistician(s) for the analysis, researcher(s) for the reporting, and construction of web reports (if done).

Equipment requirements: Computers, and software licenses.

Other resources needed: Printing of the reports, sending the laboratory and other test results to the participants, and press releases.

10.3 PREPARATION OF THE SURVEY BUDGET

Preparation of the survey budgets starts with the list of the resources needed. After that, it has to be assessed how many working days are needed for each personnel group, how many of each piece of equipment is needed and how much of the other resources

are needed so that the planned survey can be completed. After that the price per unit is determined and then the budget for each needed resource will come as the product of number of units by cost per unit. The total budget is the sum of the resource-specific budgets.

Often, much of the planning and coordination tasks of the survey is done by the public officers who do the work as part of their official duties. In cases like this, it may be difficult to define the personnel costs of their work for the budget – but this figure may not be even necessary to calculate, if additional funding is not required to cover their employment costs.

10.4 EXAMPLE OF THE NEEDED RESOURCES AND BUDGET

The following budget example is based on number of assumptions and for a hypothetical survey setting, which may be feasible in some countries but not necessary in all.

10.4.1 THE HYPOTHETICAL SURVEY SETTING

A national health examination survey will be conducted in a country without a previous national HES. This means that there is no available equipment from a previous HES which could be used in this survey, so all equipments needed must to be bought.

The survey planning will take a year (12 months). At the end of this time, training of the field work staff will be organized and a pilot survey conducted. The actual survey will be carried out during a six month period.

The survey will include the following measurements: basic anthropometric measurements (height, weight and waist circumference), blood pressure and blood samples for total and HDL-cholesterol and glucose. A questionnaire part of the survey will include questions from the European Health Interview Survey (EHIS) questionnaire. A questionnaire will be self-administered before coming to the examinations but checked by the receptionist for completion during the registration.

For the pilot survey, a sample of 200 person will be invited and for the actual survey a sample of 4 000 persons. A statistician will draw the samples from an existing sampling frame.

For the field work, four teams are needed. Each team will have a receptionist, two nurses and one laboratory technician. For the recruitment of the field work personnel, newspaper announcements are placed in five major national newspapers.

The training of the field work personnel takes place in the institute responsible for the survey organization. Training is conducted by two qualified nurses with the help from the survey coordinator, data manager, laboratory personnel and other persons responsible for the survey planning. The training will take a week (five days).

The pilot survey will follow the training and will take three days. The pilot survey will be conducted in one location which is centrally located. The premises for the pilot survey are at the local health care centre and no rent is paid. After that there will be a two-day seminar to discuss the experiences gained during the pilot and how the actual survey protocol will possibly be changed based on the experience gained.

The actual survey will be conducted in four different locations at the same time. In each location, the team will stay for a week and then move to the next place. This means that each team will re-locate 24 times and there will be a total of 96 examination sites. As field work staff are moving from location to location, their travel expenses and accommodations on site have to be paid as well as per diems. The transport of the equipment and other survey materials from location to location is done by car.

Survey invitations are sent by mail to invitees and in the invitation letter an appointment time for the examination is given. Persons can call to change their appointment if needed. If a person has not cancelled his/her appointment and does not show up to the examination, the receptionist will call the person the same day and will tries to re-schedule the appointment.

10.4.2 BUDGET CALCULATIONS

The following budget calculations are based on assumption of salaries and cost of devices/resources which may differ considerably between countries. Present values reflect estimates based on survey budgets from a few previous national HESs [1] and information obtained from a few manufactures of the devices.

It also should be remembered that this budget is only an example for this hypothetical case, and therefore will only serve as an example of what to take into account and how much the different phases could contribute to the total cost.

BUDGET FOR THE NATIONAL HEALTH EXAMINATION SURVEY IN HYPOTHETICAL SETTING

PLANNING OF THE SURVEY CONTENTS AND ORGANIZATION

Personnel costs

<i>Type of personnel</i>	<i>Person months</i>	<i>Cost (€) / person month</i>	<i>Total cost (€)</i>
Researcher	36	6 500,00 €	234 000,00 €
Data manager/IT person	8	5 000,00 €	40 000,00 €
Statistician	4	5 000,00 €	20 000,00 €
PR person	6	3 000,00 €	18 000,00 €
Laboratory person (senior)	4	4 500,00 €	18 000,00 €
Nurse	5	2 300,00 €	11 500,00 €
TOTAL			341 500,00 €

Equipment and other resources

<i>Type of resource</i>	<i>Number</i>	<i>Cost (€) / item</i>	<i>Total cost (€)</i>
Computer	3	1 000,00 €	3 000,00 €
Software for computer	3	1 000,00 €	3 000,00 €
Publicity material and adds			10 000,00 €
Sample selection services			10 000,00 €
Recruitment of field work personnel	5	500,00 €	2 500,00 €
TOTAL			26 000,00 €
TOTAL COST OF PLANNING OF THE SURVEY CONTENTS AND ORGANIZATION			367 500,00 €

TRAINING AND PILOT SURVEY**Personnel costs**

<i>Type of personnel</i>	<i>Person months</i>	<i>Cost (€) / person month</i>	<i>Total cost (€)</i>
Coordinator	0,5	8 000,00 €	4 000,00 €
Nurse	1	2 300,00 €	2 300,00 €
Laboratory person	1	3 500,00 €	3 500,00 €
Receptionist	2	2 200,00 €	4 400,00 €
Nurse	4	2 000,00 €	8 000,00 €
Laboratory technician	2	2 500,00 €	5 000,00 €
TOTAL			27 200,00 €

Equipment and other resources

<i>Type of resource</i>	<i>Number</i>	<i>Cost (€) / item</i>	<i>Total cost (€)</i>
Stadiometer	4	90,00 €	360,00 €
Beam balance scale	4	350,00 €	1 400,00 €
Measurement tape	8	5,00 €	40,00 €
Carpenters level	4	20,00 €	80,00 €
Platform	4	50,00 €	200,00 €
Full body length mirror	4	100,00 €	400,00 €
Sphygmomanometer	4	100,00 €	400,00 €
Stethoscope	4	80,00 €	320,00 €
Cuffs (set of 4 different sizes)	4	100,00 €	400,00 €
Stopwatch	4	10,00 €	40,00 €
Tourniquet	4	10,00 €	40,00 €
Blood sample collection material			5 000,00 €
Thermometer	8	5,00 €	40,00 €

Timer	4	10,00 €	40,00 €
Centrifuge	4	6 000,00 €	24 000,00 €
Computer (laptop)	8	1 000,00 €	8 000,00 €
Software for computer	8	1 000,00 €	8 000,00 €
Mobile phone	8	100,00 €	800,00 €
Internet connection for one month	8	30,00 €	240,00 €
Office supplies			50,00 €
Printed invitation letters	200	1,00 €	200,00 €
Printed questionnaires	220	5,00 €	1 100,00 €
Information letter and informed consent form	220	3,00 €	660,00 €
Reagents for blood sample analysis			1 500,00 €
Blood sample transfer containers+dry ice			200,00 €
Recruitment of participants	200	2,00 €	400,00 €
Miscellaneous costs			1 000,00 €
TOTAL			53 910,00 €
TOTAL COST OF TRAINING AND PILOT SURVEY			81 110,00 €

ACTUAL FIELD WORK INCLUDING REPORTING

Personnel cost

<i>Type of personnel</i>	<i>Person months</i>	<i>Cost (€) / person month</i>	<i>Total cost (€)</i>
Coordinator	9	6 500,00 €	58 500,00 €
Secretary	9	2 200,00 €	19 800,00 €
Data manager	9	5 000,00 €	45 000,00 €
Statistician	9	5 000,00 €	45 000,00 €
PR person	5	3 000,00 €	15 000,00 €
Laboratory person	8	4 500,00 €	36 000,00 €

Receptionist	24	2 200,00 €	52 800,00 €
Nurse	48	2 000,00 €	96 000,00 €
Laboratory technician	24	2 500,00 €	60 000,00 €
TOTAL			428 100,00 €

Equipment and other resources

<i>Type of resource</i>	<i>Number</i>	<i>Cost (€) / item</i>	<i>Total cost (€)</i>
Stadiometer	4	90,00 €	360,00 €
Beam balanced scale	2	350,00 €	700,00 €
Measurement tape	40	5,00 €	200,00 €
Carpenters level	2	20,00 €	40,00 €
Platform	2	50,00 €	100,00 €
Full body length mirror	4	100,00 €	400,00 €
Sphygmomanometer	2	100,00 €	200,00 €
Stethoscope	4	80,00 €	320,00 €
Cuffs (set of 4 different sizes)	2	100,00 €	200,00 €
Stopwatch	2	10,00 €	20,00 €
Tourniquet	4	10,00 €	40,00 €
Blood sample collection material			20 000,00 €
Thermometer	4	5,00 €	20,00 €
Timer	4	10,00 €	40,00 €
Centrifuge	1	6 000,00 €	6 000,00 €
Computer	1	1 000,00 €	1 000,00 €
Software	1	1 000,00 €	1 000,00 €
Internet connection for 7 months on field	8	210,00 €	1 680,00 €
Office supplies			1 000,00 €
Printed invitation letter	5000	1,00 €	5 000,00 €

Printed questionnaire	4400	5,00 €	22 000,00 €
Information letter and informed consent form	4400	3,00 €	13 200,00 €
Reagents for blood sample analysis			30 000,00 €
Blood sample transfer container+dry ice			8 000,00 €
Recruitment of participants	5000	2,00 €	10 000,00 €
Material transfer costs (courier)	96	200,00 €	19 200,00 €
Field work personnel travel cost	384	200,00 €	76 800,00 €
Field work personnel subsistence	1920	130,00 €	249 600,00 €
Data entry + cleaning			20 000,00 €
Deep freezer for sample storage	1	3 000,00 €	3 000,00 €
Publicity material and adds			20 000,00 €
Reports			30 000,00 €
Miscellaneous costs			20 000,00 €
TOTAL			510 120,00 €
TOTALCOST OF ACTUAL FIELD WORK INCLUDING REPORTING			938 220,00 €
 OVER ALL TOTAL			 1 386 830,00 €

Notes relating to the above budget:

1. Personnel costs are total personnel costs including all employers' expenses like insurances, etc.
2. Usually, a lot of planning work can be done by public officers who do the work as part of their official duties. In cases like this, the personnel costs usually are not directly allocated for the survey budget.
3. If questionnaires are filled in during the interview, the personnel costs will increase substantially due to the personnel costs of the interviewers.
4. In the above example budget, the information from the measurements is collected on paper forms which are then keyed in to database together with questionnaires. If measurement results are imputed on computer already on

field and questionnaires are either CAPI or CASI, the data entry costs will increase due to increasing need of computers, and software.

5. Miscellaneous costs can include for example travel cost reimbursements for participants, a small snack after blood sample collection for those participants who have fasted, etc.
6. The above budget is based on assumption that examinations are conducted at fixed clinics. In case the survey examinations are conducted at the home of the participant or on mobile clinics, the budget has to be adjusted in relation to amount of the personnel and amount of equipment required.

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11 ORGANIZING THE INTERNATIONAL COLLABORATION NEEDED BY A SYSTEM OF STANDARDIZED EUROPEAN HES

Kari Kuulasmaa¹, Arpo Aromaa¹

¹ National Public Health Institute (KTL), Helsinki, Finland

11.1 NEED FOR EUROPEAN WIDE COLLABORATION

We believe that whenever possible, the responsibility of planning and conducting a HES should be at the national level. This increases the local motivation for the HES, and is important for the selection of the nationally most important measurements. In this way also the national infrastructure and the national habits, attitudes and health information needs can be taken into account. This approach also facilitates the training of national experts for the proper analysis and interpretation of the survey results.

The review of HES in Europe conducted by the FEHES Project concluded that the only way to obtain comparable data is to use joint protocols and international co-ordination, training and quality control [1]. In order that international comparability of the HES data be possible, a responsible body will be needed which:

1. creates and maintains the European standards;
2. organizes training for the use of the standards;
3. conducts external quality control; and
4. evaluates the success of the standardization in each country.

The FEHES review report revealed that international collaboration will be needed also for:

5. providing advice to the countries in planning the national HES;

Furthermore, in order that the success of the standardization can be properly assessed, it is essential that

6. individual level data are collected in a central data repository.

This also facilitates

7. rapid basic reporting and interpretation of the results for European level uses;
and
8. easier sharing of the data with research groups for deeper analysis.

The national contact persons of the FEHES Project feel that it is easier to obtain national funding if international coordination and standardization are available.

The eight tasks identified above for international collaboration are elaborated below.

11.1.1 CREATION AND MAINTENANCE OF STANDARDS

Joint protocols have been described in this report for several key measurements in a HES. Although they are good enough so that it is useful to use them in national HES, not all of them are perfect yet. For example, it seems that mercury sphygmomanometers cannot be used long for blood pressure measurement, but there are not yet tested good alternatives. Therefore, constant attention will be needed to follow and promote new developments in measurement and data collection procedures and technology, to update the European standards when this is deemed useful, and to keep the agreed standards available to those who plan and conduct HESs.

This report does not yet describe standard protocols for all measurements that have been taken in HESs in the past, or that will be planned for future HES. Any measurements that will be used on the future should be evaluated. When found appropriate, European standard procedures should be recommended for them and made available to other countries planning to include these measurements in their HESs.

11.1.2 TRAINING TO USE THE EUROPEAN STANDARDS, QUALITY CONTROL AND EVALUATION OF THE SUCCESS OF THE STANDARDIZATION

Training and quality control should be an integral part of the local operations of the national surveys. To facilitate the standardization between the countries, international collaboration in training and quality control will be necessary. Common training

material, such as audiovisual tapes for training of blood pressure measurers need to be produced. This is also well reflected in the views of the national contact persons of the FEHES Project. 31 out of 32 contact persons considered international quality control important [1].

A specific area where an international facility is needed is laboratory standardization and quality control. From the 1970s to 1990s, lipid standardization in Europe was carried out by WHO Regional Lipid Reference Centre (RLRC) in Prague, Czech Republic. Now, as WHO RLRC is no longer operating, it is important to establish a replacement to serve European surveys. A reference laboratory is needed for providing secondary calibrators for the survey laboratories as well as providing external quality control. For American surveys, the standardization has been in the hands of the Centers for Disease Control (CDC) Atlanta for several decades using methods which guarantee stability of the reference values over the years. Without a laboratory reference centre with sufficient expertise and established reference methods, there is no way to guarantee the validity of time trends within countries or the comparability of results between countries.

After surveys have been conducted, assessment of the quality of the data, the success of the standardization and documentation of country-specific characteristics of the data are prerequisites for meaningful comparisons of the survey results between countries. This should be done through a centre that is independent of the national surveys. Past experience has shown that many shortcomings found in the data can still be remedied at this stage.

11.1.3 ADVICE TO THE COUNTRIES IN PLANNING THE NATIONAL HES

The review of experience in the countries for conducting a HES revealed that there is generally much more expertise than we anticipated [1]. Nevertheless, it is also important that the countries can make as much use as possible of the experiences from the other countries. Therefore, it is important that efficient forums are organized for the open exchange of experiences, and that direct links are established between the countries with past HES and the less experienced countries. In addition to planning the field work and budgeting the surveys, international advice and/or review of the plans are needed for the sampling design and ethical and legal issues. The same concerns the measurement procedures in countries with previous national HES. Even if the measurement procedure used in the past differs from the European standard procedure, it is desirable to achieve international comparability and also to be able to follow trends from the past. An optimal compromise will need to be found in such cases.

Of the 32 national contact persons of the FEHES Project, 29 considered international expert consultation important [1].

11.1.4 POOLING INDIVIDUAL LEVEL DATA FOR QUALITY ASSESSMENT, JOINT REPORTING AND SHARING FOR DEEPER ANALYSIS

The analysis of survey data for the national purposes should primarily be done locally in each country. The countries should be encouraged to utilize the data as extensively as possible, not only for policy making and public health purposes, but also for research. Although public health would be the main motivation for the monitoring, its use for research helps in creating national expertise in interpreting the data and in improving the quality of the data.

The collection of individual level data from each country to a central database is necessary for the evaluation of the success of the standardization. At the same time it facilitates rapid basic reporting and interpretation of the results for European level uses, such as the EUPHIX database [2]. The pooled database also facilitates sharing of the data with research groups that can undertake deeper analysis of the results than is possible in the basic rapid reporting.

Principles and rules for sharing individual level HES data need to be developed, covering the transfer of data from the countries, possible access of third parties for analyzing the pooled data and the publication of the results. The principles must respect the rights and interest of all parties.

11.2 ORGANIZING THE INTERNATIONAL COLLABORATION

A central coordination with sufficient expertise should be established with the responsibility to facilitate the national surveys by:

- Creating, maintaining and disseminating the European standards;
- Providing training material and organizing training for the use of the standard procedures for the persons responsible of the training of the national survey teams;
- Coordinating external quality control and preparing guidelines for and monitoring of internal quality control;
- Evaluating the success of the standardization in each survey. The results would be discussed with the organizers of the surveys, and made

available to all who will be using the data. Summaries would accompany the basic reports of the survey results;

- Providing advice to the countries in planning a national HES and coordinating a network of the organizers of national surveys for sharing experience and exchanging expertise in organizing surveys, data collection and reporting. It is important that the experience gained by countries from earlier HESs will be available to all other countries;
- Collecting the individual level data from the countries for quality assessment, basic reporting and sharing with research groups. It is important that the security and confidentiality of such data will be assured. Principles and rules for such data collection, analysis and sharing will need to be developed and agreed by the countries before any data are collected. The rules and principles must respect the rights and interests of all parties;
- Undertaking rapid basic reporting and interpretation of the results for European level uses; and
- Managing the sharing of the data with research groups for deeper analysis.

The central coordination should be funded by the EU, and operate in collaboration with EU, WHO, OECD and other agencies.

The review conducted by the FEHES Project reveals that there are 17 countries with active plans for a national HES in the next five years, and some of these countries are planning to start their HES already in 2009 [1]. Therefore, the European infrastructure for a joint standardization of HESs should be established as soon as possible. The first task is to facilitate the planning and the standardization of national HESs in the countries that plan to start their HESs in the next few years. This task fits well with the priority topic of the Work Plan of EU's Health Programme for 2008 to implement a pilot European Health Examination Survey in some member states. This would be funded through a call for tender. Based on the experiences from the pilot, more permanent structures should be established in 2010, to take the responsibility of the tasks specified above for the remaining European countries, and for the next round of surveys in the pilot countries. The total annual costs of such a central coordination would be about 2-3 million euro per year.

The required expertise for such a central coordination is presently available primarily at the national public health institutes of a number of European countries with past experience on national HESs. Therefore, we propose that for the time being the central coordination is set up as a consortium between several such institutes, possibly including other institutes with needed expertise on specific fields, such as on sampling methods. In the longer term a more permanent body might be established. In addition to the work needed for HESs, it could possibly cover also other areas of health monitoring health monitoring.

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ANNEX1. QUESTIONNAIRE ITEMS

CORE QUESTIONS

AGE

Modified from EHIS.

How many persons live in the household, including yourself? (HH.1 in EHIS)

persons

How many of these persons are less than 18 years of age? (HH.2 in EHIS)

persons

SEX

☐ Men

☐ Women

EDUCATION

What is the highest education leaving certificate, diploma or education degree you have obtained? Please include any vocational training. (HH.7 in EHIS)

(Note: The response categories should be named according to the educational system of the country.)

☐ no formal education or below

☐ primary education

☐ lower secondary education

☐ upper secondary education

☐ post-secondary but non-tertiary education

☐ first stage of tertiary education

☐ second stage of tertiary education

How many years in total have you spent in school or in full-time study? (SES1 in EHRM)

|_|_| years

OCCUPATION

How would you define your current labour status? (HH.8 in EHIS)

- ☐ working for pay or profit (including unpaid work for a family business or holding, including an apprenticeship or paid traineeship, including currently not at work due to maternity, parental, sick leave or holidays)
- ☐ unemployed
- ☐ pupil, student, further training, unpaid work experience
- ☐ in retirement or early retirement or has given up business
- ☐ permanently disabled
- ☐ in compulsory military or community service
- ☐ fulfilling domestic tasks
- ☐ other. Please specify: _____

Have you ever worked for pay or profit? (HH.9 in EHIS)

- ☐ Yes
- ☐ No → GO TO NEXT MODULE

Are (Were) you an employee, self-employed or working without payment as a family worker?(HH.10 in EHIS)

- ☐ employee
- ☐ self-employed → GO TO QUESTION OC.5 in EHIS
- ☐ family worker → GO TO QUESTION OC.5 in EHIS

What type of work contract do (did) you have? (HH.11 in EHIS)

- ☐ permanent job/work contract of unlimited duration
- ☐ temporary job/work contract of limited duration

In your (main) job do (did) you work full-time or part-time? (HH.12 in EHIS)

- ☐ full-time
- ☐ part-time

What is (was) your occupation in this job? (HH.13 in EHIS)

Job title: _____

Describe what do (did) you mainly do in your job: _____

What does (did) the business/organisation mainly produce or do at the place where you work (worked) (e.g. chemical, fishing, hotel/restaurant, health and social work, etc.)? (HH.14 in EHIS)

INCOME

Which kinds of income you and the other members of your household receive? (Multiple answers are possible) (IN.1 in EHIS)

- ☐ Income from work (as employee or self-employed)
- ☐ Unemployment benefits
- ☐ Old-age or survivor's benefits
- ☐ Sickness or disability benefits
- ☐ Family/children related allowances
- ☐ Housing allowances
- ☐ Education-related allowance
- ☐ Other regular benefits
- ☐ No source of income
- ☐ Don't know

What is your household's total net monthly income (that is after deductions for tax, National Insurance etc.)? (IN.2 in EHIS)

- ☐ Yes
- ☐ No → GO TO QUESTION IN.4 in EHIS

What is your household's total net income per month (if known)? (IN.3 in EHIS)

Amount |__|__|__|__|__|__|__| (national currency)

Which group represents your household's total net monthly income from all these sources after deductions for income tax, National Insurance etc. Please tick one. (IN.4 in EHIS) *(Note: The values of the deciles' limits for each country should be used)*

- ☐ below 1st decile
- ☐ between 1st decile and 2nd decile
- ☐ between 2nd decile and 3rd decile
- ☐ between 3rd decile and 4th decile
- ☐ between 4th decile and 5th decile
- ☐ between 5th decile and 6th decile
- ☐ between 6th decile and 7th decile
- ☐ between 7th decile and 8th decile
- ☐ between 8th decile and 9th decile
- ☐ above 9th decile
- ☐ Refuse to answer

GENERAL HEALTH/HEALTH STATUS

How is your health in general? (HS.1 in EHIS)

- ☐ very good
- ☐ good
- ☐ fair
- ☐ bad
- ☐ very bad
- ☐ don't know
- ☐ refusal

Do you have any longstanding illness or [longstanding] health problem? [Longstanding here means illnesses or health problems which have lasted, or are expected to last, for 6 months or more]. (HS.2 in EHIS)

- ☐ Yes
- ☐ No
- ☐ don't know
- ☐ refusal

For at least the past 6 months, to what extent have you been limited because of a health problem in activities people usually do? (HS.3 in EHIS)

- ☐ severely limited
- ☐ limited but not severely or
- ☐ not limited at all?
- ☐ don't know
- ☐ refusal

**Do you have or have you ever had any of the following diseases or conditions?
Tick all that apply (HS.4 in EHIS)**

- ☐ Asthma (allergic asthma included)
- ☐ Chronis bronchitis, chronic obstructive pulmonary disease, emphysema
- ☐ Myocardial infarction
- ☐ Coronary heart disease (angina pectoris)
- ☐ High blood pressure (hypertension)
- ☐ Stroke (cerebral haemorrhage, cerebral thrombosis)
- ☐ Rheumatoid arthritis (inflammation of the joints)
- ☐ Osteoarthritis (arthrosis, joint degeneration)
- ☐ Low back disorder or other chronic neck defect
- ☐ Neck disorder or other chronic neck defect
- ☐ Diabetes
- ☐ Allergy, such as rhinitis, eye inflammation, dermatitis, food allergy or other (allergic asthma excluded)
- ☐ Stomach ulcer (gastric or duodenal ulcer)
- ☐ Cirrhosis of the liver, liver dysfunction
- ☐ Cancer (malignant tumour, also including leukaemia and lymphoma)
- ☐ Severe headache such as migraine
- ☐ Urinary incontinence, problems in controlling the bladder
- ☐ Chronic anxiety
- ☐ Chronic depression
- ☐ Other mental health problems
- ☐ Permanent injury or defect caused by an accident

Do you have or have you ever had any of the following diseases or conditions diagnosed by a medical doctor? Tick all that apply (HS.5 in EHIS)

- ☐ Asthma (allergic asthma included)
- ☐ Chronis bronchitis, chronic obstructive pulmonary disease, emphysema
- ☐ Myocardial infarction
- ☐ Coronary heart disease (angina pectoris)
- ☐ High blood pressure (hypertension)
- ☐ Stroke (cerebral haemorrhage, cerebral thrombosis)
- ☐ Rheumatoid arthritis (inflammation of the joints)
- ☐ Osteoarthritis (arthrosis, joint degeneration)
- ☐ Low back disorder or other chronic neck defect
- ☐ Neck disorder or other chronic neck defect
- ☐ Diabetes
- ☐ Allergy, such as rhinitis, eye inflammation, dermatitis, food allergy or other (allergic asthma excluded)
- ☐ Stomach ulcer (gastric or duodenal ulcer)
- ☐ Cirrhosis of the liver, liver dysfunction
- ☐ Cancer (malignant tumour, also including leukaemia and lymphoma)
- ☐ Severe headache such as migraine
- ☐ Urinary incontinence, problems in controlling the bladder
- ☐ Chronic anxiety
- ☐ Chronic depression
- ☐ Other mental health problems
- ☐ Permanent injury or defect caused by an accident

Do you have or have you had in past 12 months any of the following diseases or conditions? Tick all that apply (HS.6 in EHIS)

- ☐ Asthma (allergic asthma included)
- ☐ Chronis bronchitis, chronic obstructive pulmonary disease, emphysema
- ☐ Myocardial infarction
- ☐ Coronary heart disease (angina pectoris)
- ☐ High blood pressure (hypertension)
- ☐ Stroke (cerebral haemorrhage, cerebral thrombosis)
- ☐ Rheumatoid arthritis (inflammation of the joints)
- ☐ Osteoarthritis (arthrosis, joint degeneration)
- ☐ Low back disorder or other chronic neck defect
- ☐ Neck disorder or other chronic neck defect
- ☐ Diabetes
- ☐ Allergy, such as rhinitis, eye inflammation, dermatitis, food allergy or other (allergic asthma excluded)
- ☐ Stomach ulcer (gastric or duodenal ulcer)
- ☐ Cirrhosis of the liver, liver dysfunction
- ☐ Cancer (malignant tumour, also including leukaemia and lymphoma)
- ☐ Severe headache such as migraine
- ☐ Urinary incontinence, problems in controlling the bladder
- ☐ Chronic anxiety
- ☐ Chronic depression
- ☐ Other mental health problems
- ☐ Permanent injury or defect caused by an accident

SMOKING

Do you smoke at all nowadays? (SK.1 in EHIS)

- ☐ Yes, daily
- ☐ Yes, occasionally → GO TO QUESTION SK.4 in EHIS
- ☐ Not at all → GO TO QUESTION SK.4 in EHIS

What tobacco product do you smoke each day? (*More answers are possible*) (SK.1 in EHIS)

- ☐ Manufactured cigarettes
- ☐ Hand-rolled cigarettes
- ☐ Cigars
- ☐ Pipefuls of tobacco
- ☐ Other

On average, how many cigarettes, cigars or pipefuls do you smoke each day? (SK.3 in EHIS)

Manufactured cigarettes	<input type="text"/> <input type="text"/> <input type="text"/>
Hand-rolled cigarettes	<input type="text"/> <input type="text"/> <input type="text"/>
Cigars	<input type="text"/> <input type="text"/> <input type="text"/>
Pipefuls of tobacco	<input type="text"/> <input type="text"/> <input type="text"/>
Other	<input type="text"/> <input type="text"/> <input type="text"/>

Have you ever smoked (cigarettes, cigars, pipes) daily, or almost daily, for at least one year? (SK.4 in EHIS)

- ☐ Yes
- ☐ No → GO TO QUESTION SK.6 in EHIS

For how many years have you smoked daily? Count all separate periods of smoking daily. If you don't remember the exact number of years, please give an estimate. (SK.5 in EHIS)

years

How often are you exposed to tobacco smoke indoors at home? (SK.6 in EHIS)

- ☐ Never or almost never
- ☐ Less than 1 hour per day
- ☐ 1-5 hours a day
- ☐ More than 5 hours a day

How often are you exposed to tobacco smoke indoors in public places and transport (bars, restaurants, shopping malls, arenas, bingo halls, bowling alleys, trains, metro, bus)? (SK.7 in EHIS)

- ☐ Never or almost never
- ☐ Less than 1 hour per day
- ☐ 1-5 hours a day
- ☐ More than 5 hours a day

How often are you exposed to tobacco smoke indoors at your workplace? (SK.8 in EHIS)

- ☐ Never or almost never
- ☐ Less than 1 hour per day
- ☐ 1-5 hours a day
- ☐ More than 5 hours a day
- ☐ Not relevant (don't work or don't work indoors)

ADDITIONAL QUESTIONS**ALCOHOL CONSUMPTION**

During the past 12 months, how often have you had an alcoholic drink of any kind (that is beer, wine, spirits, liqueurs or other alcoholic beverages)? (AL.1 in EHIS)

- ☐ Never → GO TO NEXT MODULE
- ☐ Monthly or less → GO TO NEXT MODULE
- ☐ 2 to 4 times a month → GO TO QUESTION AL.3 in EHIS
- ☐ 2 to 3 times a week
- ☐ 4 to 6 times a week
- ☐ Every day

How many drinks containing alcohol do you have each day in a typical week when you are drinking? Start with Monday and take one day at a time. (AL.2 in EHIS)

	<i>No. of drinks</i>		<i>No. of drinks</i>		<i>No. of drinks</i>		<i>No. of drinks</i>		<i>No. of drinks</i>	
Monday	Beer	_ _	Wine	_ _	Liqueur	_ _	Spirits	_ _	Other local alcoholic beverage	_ _
Tuesday	Beer	_ _	Wine	_ _	Liqueur	_ _	Spirits	_ _	Other local alcoholic beverage	_ _
Wednesday	Beer	_ _	Wine	_ _	Liqueur	_ _	Spirits	_ _	Other local alcoholic beverage	_ _
Thursday	Beer	_ _	Wine	_ _	Liqueur	_ _	Spirits	_ _	Other local alcoholic beverage	_ _
Friday	Beer	_ _	Wine	_ _	Liqueur	_ _	Spirits	_ _	Other local alcoholic beverage	_ _
Saturday	Beer	_ _	Wine	_ _	Liqueur	_ _	Spirits	_ _	Other local alcoholic beverage	_ _
Sunday	Beer	_ _	Wine	_ _	Liqueur	_ _	Spirits	_ _	Other local alcoholic beverage	_ _

During the past 12 months, how often did you have 6 or more drinks on one occasion? (AL.3 in EHIS)

- ☐ Never
- ☐ Less than monthly
- ☐ Monthly
- ☐ Weekly
- ☐ Daily or almost daily

USE OF MEDICATIONS

During the past two weeks, have you used any medicines (including dietary supplements such as herbal medicines or vitamins and for women, including contraceptive pills or other hormones) that were prescribed or recommended for you by a doctor? (MD.1 in EHIS)

- ☐ Yes
- ☐ No → GO TO QUESTION MD.3 in EHIS
- ☐ don't know → GO TO QUESTION MD.3 in EHIS
- ☐ refusal _ 9 → GO TO QUESTION MD.3 in EHIS

**Were they medicines for any of these conditions? Please tick all that applies.
(MD.2 in EHIS)**

- ☐ Asthma
- ☐ Chronic bronchitis, chronic obstructive pulmonary disease, emphysema
- ☐ High blood pressure
- ☐ Lowering the blood cholesterol level
- ☐ Other cardiovascular disease, such as stroke and heart attack
- ☐ Pain in the joints (arthrosis, arthritis)
- ☐ Pain in the neck or back
- ☐ Headache or migraine
- ☐ Other pain
- ☐ Diabetes
- ☐ Allergic symptoms (eczema, rhinitis, hay fever)
- ☐ Stomach troubles
- ☐ Cancer (chemotherapy)
- ☐ Depression
- ☐ Tension or anxiety

Have you used other types of medicines that were prescribed to you? (MD.2 in EHIS)

- ☐ Sleeping tablets
- ☐ Antibiotics such as penicillin (or any other national relevant example)
- ☐ Contraceptive pills
- ☐ Hormones for menopause
- ☐ Some other medicines prescribed by a doctor. What type of medicines?

During the past two weeks, have you used any medicines or dietary supplement or herbal medicines or vitamins not prescribed or recommended by a doctor? (MD.3 in EHIS)

- ☐ Yes
- ☐ No → GO TO NEXT MODULE
- ☐ don't know → GO TO NEXT MODULE
- ☐ refusal → GO TO NEXT MODULE

Were they medicines or supplements for these conditions? Tick all that applies. (MD.4 in EHIS)

- ☐ Pain in the joints (arthrosis, arthritis)
- ☐ Headache or migraine
- ☐ Other pain
- ☐ Cold, flu or sore throat
- ☐ Allergic symptoms (eczema, rhinitis, hay fever)
- ☐ Stomach trouble
- ☐ Or were they vitamins, minerals or tonics
- ☐ Or some other type or medicine or supplement? Please specify:

USE OF HEALTH SERVICES (GENERAL/ FOR SPECIFIC CONDITIONS)

During the past 12 months, that is since (date one year ago), have you been in hospital as an inpatient, that is overnight or longer? (HC.1 in EHIS)

- ☐ Yes
- ☐ No → GO TO QUESTION HC.4 in EHIS
- ☐ don't know → GO TO QUESTION HC.4 in EHIS
- ☐ refusal → GO TO QUESTION HC.4 in EHIS

How many separate stays in hospital as an inpatient have you had since (date one year ago)? Count all the stays that ended in this period. (HC.2 in EHIS)

stays

- ☐ don't know
- ☐ refusal

Thinking of this/these inpatient stay(s), how many nights in total did you spend in hospital? (HC.3 in EHIS)

nights

- ☐ don't know
- ☐ refusal

During the past 12 months, that is since (date one year ago), have you been admitted to hospital as a day patient, that is admitted to a hospital bed, but not required to remain overnight? (HC.4 in EHIS)

- ☐ Yes
- ☐ No → GO TO QUESTION HC.6 in EHIS
- ☐ don't know → GO TO QUESTION HC.6 in EHIS
- ☐ refusal → GO TO QUESTION HC.6 in EHIS

How many days have you been admitted as a day patient since (date one year ago)? (HC.5 in EHIS)

days

- ☐ don't know
- ☐ refusal

During the past 12 months, was there any time when you really needed to be hospitalised following a recommendation from a doctor, either as an inpatient or a day patient, but did not? (HC.6 in EHIS)

- ☐ Yes, there was at least one occasion
- ☐ No, there was no occasion → GO TO NEXT MODULE
- ☐ don't know → GO TO NEXT MODULE
- ☐ refusal → GO TO NEXT MODULE

What was the main reason for not being hospitalised? (HC.7 in EHIS)

- ☐ Could not afford to (too expensive or not covered by the insurance fund)
- ☐ Waiting list, other reasons due to the hospital
- ☐ Could not take time because of work, care for children or for others
- ☐ Too far to travel / no means of transportation
- ☐ Fear of surgery / treatment
- ☐ Other reason
- ☐ don't know
- ☐ refusal

When was the last time you consulted a GP (general practitioner) or family doctor on your own behalf? (Please, include visits to your doctor's practice as well as home visits and consultations by telephone.) (HC.10 in EHIS)

- ☐ Less than 12 months ago
- ☐ 12 months ago or longer → GO TO NEXT MODULE
- ☐ Never → GO TO NEXT MODULE
- ☐ don't know → GO TO NEXT MODULE
- ☐ refusal → GO TO NEXT MODULE

During the past four weeks ending yesterday, that is since (date), how many times did you consult a GP (general practitioner) or family doctor on your own behalf? (Mark 0 if not at all.) (HC.11 in EHIS)

- times
- ☐ don't know
 - ☐ refusal

HC.12 When was the last time you consulted a medical or surgical specialist on your own behalf? (Include visits to doctors as outpatient or emergency departments only, but not include contact while in hospital as an in-patient or day-patient. Also include visits to doctors at the workplace or school.) (HC.12 in EHIS)

- ☐ Less than 12 months ago
- ☐ 12 months ago or longer → GO TO QUESTION HC.14 in EHIS
- ☐ Never → GO TO QUESTION HC.14 in EHIS
- ☐ don't know → GO TO QUESTION HC.14 in EHIS
- ☐ refusal → GO TO QUESTION HC.14 in EHIS

During the past four weeks ending yesterday, that is since (date), how many times did you consult a specialist on your own behalf? (Mark 0 if not at all.) (HC.13 in EHIS)

times

- ☐ don't know
- ☐ refusal

Was there any time during the past 12 months when you really needed to consult a specialist but did not? (HC.14 in EHIS)

- ☐ Yes, there was at least one occasion
- ☐ No, there was no occasion → GO TO QUESTION HC.16 in EHIS
- ☐ don't know → GO TO QUESTION HC.16 in EHIS
- ☐ refusal → GO TO QUESTION HC.16 in EHIS

What was the main reason for not consulting a specialist? (HC.15 in EHIS)

- ☐ Could not afford to (too expensive or not covered by the insurance fund)
- ☐ Waiting list, don't have the referral letter
- ☐ Could not take time because of work, care for children or for others
- ☐ Too far to travel / no means of transportation
- ☐ Fear of doctor / hospitals / examination / treatment
- ☐ Wanted to wait and see if problem got better on its own
- ☐ Didn't know any good specialist
- ☐ Other reason
- ☐ don't know
- ☐ refusal

During the past 12 months, that is since (date on year ago), have you visited on your own behalf? (HC.16 in EHIS)

	Yes	No	Don't know	Refusal
Medical laboratory, radiology center	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Physiotherapist/ kinesitherapist	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Nurse, midwife (excluding when being in hospitalized, for home care services or in a medical laboratory or radiology centre)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Dietician	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Speech therapist	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Chiropractor, manual therapist	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Occupational therapist	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Psychologist or psychotherapist	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other paramedics	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

HC.17 During the past 12 months, that is since (date on year ago), have you visited on your own behalf? (HC.17 in EHIS)

	Yes	No	Don't know	Refusal
Homeopath	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Acupuncturist	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Phytotherapist/ herbalist	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other alternative medicine practitioner	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

During the past 12 months, have you yourself used any of the following care services? (HC.18 in EHIS)

	Yes	No	Don't know	Refusal
Home care service provided by a nurse or midwife	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Home help for the housework or for elderly people	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
“Meals on wheels”	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Transport service	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other home care services	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

PHYSICAL ACTIVITY

During the past 7 days, on how many days did you do vigorous physical activities? (Think only about those physical activities that you do for at least 10 minutes at a time. The vigorous physical activity makes you breathe much harder than normal and may include heavy lifting, digging, aerobics, or fast bicycling.) (PE.1 in EHIS)

Days per week

☐ don't know

☐ refusal

During the past 7 days, how much time did you spend doing vigorous physical activities? (PE.2 in EHIS)

hours minutes

☐ don't know

☐ refusal

During the past 7 days, on how many days did you do moderate physical activities? (This only about those physical activities that you do for at least 10 minutes at a time. The moderate physical activity makes you breathe somewhat harder than normal and may include walking.) (PE.3 in EHIS)

Days per week

☐ don't know

☐ refusal

During the past 7 days, how much time did you spend doing moderate physical activities? (PE.4 in EHIS)

hours minutes

☐ don't know

☐ refusal

During the past 7 days, on how many days did you walk for at least 10 minutes at a time? (Think only about the walking that you do for at least 10 minutes at a time. This includes walking at work and at home, walking to travel from place to place, and any other walking that you might do solely for recreation, sport, exercise, or leasure.) (PE.5 in EHIS)

Days per week

☐ don't know

☐ refusal

During the past 7 days, how much time did you spend walking? (PE.6 in EHIS)

hours minutes

☐ don't know

☐ refusal

FRUITS AND VEGETABLES

How often do you eat fruits (excluding juice)? (FV.1 in EHIS)

- ☐ Twice or more a day
- ☐ Once a day
- ☐ Less than once a day but at least 4 times a week
- ☐ Less than 4 times a week, but at least once a week
- ☐ Less than once a week
- ☐ Never
- ☐ don't know
- ☐ refusal

How often do you eat vegetables or salad (excluding juice and potatoes)? (FV.2 in EHIS)

- ☐ Twice or more a day
- ☐ Once a day
- ☐ Less than once a day but at least 4 times a week
- ☐ Less than 4 times a week, but at least once a week
- ☐ Less than once a week
- ☐ Never
- ☐ don't know
- ☐ refusal

How often do you drink fruit- or vegetable - juice? (FV.3 in EHIS)

- ☐ Twice or more a day
- ☐ Once a day
- ☐ Less than once a day but at least 4 times a week
- ☐ Less than 4 times a week, but at least once a week
- ☐ Less than once a week
- ☐ Never
- ☐ don't know
- ☐ refusal

SOCIAL SUPPORT**How many people are so close to you that you can count on them if you have serious personal problem? (EN.4 in EHIS)**

- ☐ None
- ☐ 1 or 2
- ☐ 3 to 5
- ☐ More than 5
- ☐ don't know
- ☐ refusal

MENTAL HEALTH

A question on mental health is on question H.S.6 of the EHIS (see above General health /health status).

ORAL HEALTH

When was the last time you visited a dentist or orthodontist on your own behalf (that is, not while only accompanying a child, spouse, etc.)? (DE.1 in EHIS)

- ☐ Less than 12 months ago
- ☐ 12 months ago or longer → GO TO NEXT MODULE
- ☐ Never → GO TO NEXT MODULE
- ☐ don't know → GO TO NEXT MODULE
- ☐ refusal → GO TO NEXT MODULE

During the past four weeks ending yesterday, that is since (date), how many times did you visit a dentist or orthodontist on your own behalf? (Mark 0 if not at all.) (DE.2 in EHIS)

times

- ☐ don't know
- ☐ refusal

ANNEX 2. LIST OF FEHES COLLABORATORS

MAIN PARTNER

Finland

Arpo Aromaa, National Institute of Public Health, Helsinki
 Päivikki Koponen, National Institute of Public Health, Helsinki
 Kari Kuulasmaa (Leader), National Institute of Public Health, Helsinki
 Markku Mähönen, National Institute of Public Health, Helsinki
 Sanna Natunen, National Institute of Public Health, Helsinki
 Liisa Penttilä, National Institute of Public Health, Helsinki
 Hanna Tolonen, National Institute of Public Health, Helsinki

ASSOCIATED PARTNERS

Italy

Susanna Conti, Italian National Institute of Public Health, Rome
 Mark Kanieff, Italian National Institute of Public Health, Rome
 Grazia Rago, Italian National Institute of Public Health, Rome

Netherlands

Monique Verschuren, National Institute for Public Health and the Environment, Bilthoven
 Lucie Viet, National Institute for Public Health and the Environment, Bilthoven

Norway

Sidsel Graff-Iversen, Norwegian Public Health Institute, Oslo
 Liv Grøtvedt, Norwegian Public Health Institute, Oslo
 Johan Heldal, Statistics Norway, Oslo

United Kingdom

Moushumi Chaudhury, University College London, London
 Jennifer Mindell, University College London, London
 Paola Primatesta, University College London, London

**OTHER COUNTRY CONTACT PERSONS AND THE PARTICIPANTS OF
 THE WORKSHOP ON HEALTH EXAMINATION SURVEYS, LUXEMBOURG,
 9-11 APRIL 2008**

Austria

Günter Diem, Arbeitskreis für Vorsorge- und Sozialmedizin, Bregenz

Belgium

Jean Tafforeau, Scientific Institute of Public Health (IPH), Brussels

Bulgaria

Christian Griva National Center of Health Informatics, Sofia

Canada

Jeanine Bustros, Statistics Canada, Ottawa

Croatia

Marina Kuzman Croatian National Institute of Public Health, Zagreb

Vlasta Deckovic-Vukres, Croatian National Institute of Public Health, Zagreb

Cyprus

Pavlos Pavlou, Ministry of Health, Nicosia

Maria Athanasiadou, Ministry of Health, Nicosia

Czech Republic

Ruzena Kubinova, National Institute of Public Health, Prague

Denmark

Torben Jørgensen, Research Centre for Prevention and Health, Glostrup University Hospital, Glostrup

Louise Eriksen, National Institute of Public Health, University of Southern Denmark, Copenhagen

Estonia

Luule Sakkeus, National Institute for Health Development, Tallinn

Merike Rätsep, National Institute for Health Development, Tallinn

Former Yugoslavian Republic of Macedonia

Vladimir Kendrovski, Republic Institute for Health Protection, Skopje

France

Juliette Bloch, Institut de Veille Sanitaire, Paris

Marie-Cristin Delmas, French Institute for Health Surveillance, Paris

Germany

Christa Scheidt-Nave, Robert Koch Institute (RKI), Berlin

Cornelia Lange, Robert Koch Institute (RKI), Berlin

Greece

Antonia Trichopoulou, Hellenic Health Foundation Ελληνικό Ίδρυμα Υγείας (HHF), Athens

Hungary

Zoltán Vokó Department of Biostatistics and Epidemiology, Faculty of Public Health, Medical and Health Science Centre, University of Debrecen, Debrecen

Iceland

Matthias Halldorsson, Directorate of Health, Seltjarnarnes

Kristjan Oddsson, Directorate of Health, Seltjarnarnes

Ireland

Cecily Kelleher, UCD School of Public Health and Population Science, Dublin

Italy

Simona Giampaoli, Italian National Institute of Public Health, Rome

Latvia

Girts Brigis, Department of Public Health and Epidemiology, Riga Stradins University, Riga

Lithuania

Vilius Grabauskas, Kaunas University of Medicine (KMU), Kaunas

Luxembourg

Marie-Lise Lair, Centre de Recherche Public-Santé, Luxembourg

Hartmunt Buchow, Eurostat

Albane Courdol, Eurostat

Guy Dargent, Public Health Executive Agency (PHEA)

Nick Fahy, European Commission, DG Sanco C2

Fabianne Lefebure, European Commission, DG Sanco C2

Antoni Montserrat, European Commission, DG Sanco C2

Malta

Renzo Pace Asciak, Department of Health Information, Ministry of Health, the Elderly and Community

Netherlands

Leonie Venmans, National Institute for Public Health and the Environment, Bilthoven

Norway

Heidi Lyshol, Norwegian Public Health Institute, Oslo

Poland

Grazyna Broda, Department of CVD Epidemiology and Prevention, National Institute of Cardiology, Warsaw

Portugal

Carlos Matias Dias, Centre for Epidemiology and Biostatistics, National Health Observatory, National Institute of Health Dr. Ricardo Jorge, Lisbon

Romania

Ioana Pertache, National Centre for Health Statistics, Bucharest

Anca Coricovac, National Centre for Health Statistics, Bucharest

Slovakia

Mária Avdicová, Regional Authority of Public Health, Banska Bystrica

Slovenia

Zlatko Fras, University Medical Centre Ljubljana (KCLJ), Ljubljana

Spain

Enric Duran, Institut Municipal d'Investigació Mèdica (IMIM), Barcelona

Carmen Rodriguez Blas, Ministry of Health and Consumer Affairs, Madrid

Sweden

Birgitta Stegmayr, University of Umeå, Umeå

Turkey

Zafer Oztek, Department of Public Health, Hacettepe University, Ankara

Toker Erguder (former contact person), Tobacco Control Department, Ministry of Health, Ankara

United Kingdom

Hugh Markowe, Department of Health, London

USA

Clifford Johnson, Center for Disease Control, Atlanta

Organizations

Piotr Kramarz, European Centre for Disease Prevention and Control, Stockholm,
Sweden

Leanne Riley, WHO/HG, Geneva, Switzerland

Istvan Szabo, European Consensus Network